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USHAŞ ULUSLARARASI SAĞLIK HİZMETLERİ A.Ş.



2020 FAALİYET RAPORU



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1- GENEL BİLGİLER

Raporun Ait Olduğu Dönem : 01.01.2020-31.12.2020
Ticaret Unvanı : USHAŞ ULUSLARARASI SAĞLIK HİZMETLERİ A.Ş.
Ticaret Sicili Numarası : 430067
Merkez Adresi : Sağlık Bakanlığı Bilkent Yerleşkesi Üniversiteler Mah. Dumlupınar Bul. 6001. Cad. No: 9 Kat: 8 Çankaya 06800 Ankara, Türkiye

İletişim Bilgileri

- Telefon : (312) 585 25 39
- Faks : (312) 585 25 67
- E-Posta Adresi : info@ushas.com.tr
- İnternet Sitesi Adresi : <https://www.ushas.com.tr/>

1.1.Şirketin Organizasyon, Sermaye ve Ortaklık Yapısı:

Şirket 10.000.000 ₺ sermaye ile kurulmuş ve kuruluş sermayesi Ankara Ticaret Sicil Müdürlüğü'ne tescil ettirilerek 04.02.2019 tarih ve 9759 sayılı Türkiye Ticaret Sicili Gazetesinde ilan edilmiştir.

1.2.Şirketin Yönetim Organı, Üst Düzey Yönetici ve Personel Bilgileri:

a) Şirketin Yönetim Organı:

Şirketin yönetimi 5 kişiden oluşan Yönetim Kurulu tarafından yürütülmektedir. Cevat ŞENGÜL'ün istifası üzerinde Yönetim Kurulu Üyeliği görevi 12.06.2020 tarihli ve 10096 nolu Ticaret Sicil Gazetesinin 31 no'lu sayfasında tescil ve ilan edilerek sona ermiştir. Yönetim Kurulu Üyeliklerine 28.07.2020 tarihli Olağanüstü Genel Kurul Toplantısında aşağıda belirtilen kişiler 31.01.2022 tarihine kadar görev yapmak üzere seçilmiştir. Salih Kenan Şahin Yönetim Kurulu Üyesi seçilmiş, Ahmet TEKİN'in Yönetim Kurulu Başkanlığı görevi sona ererek temsile yetkili olarak seçilmiş, yerine Salih Kenan ŞAHİN Yönetim Kurulu Başkanı seçilmiştir. Söz konusu değişiklik 04.08.2020 tarih 10130 sayılı Türkiye Ticaret Sicil Gazetesinde ilan edilmiştir.

Adı-Soyadı

Salih Kenan ŞAHİN
Mehmet Ali KILIÇKAYA
Ahmet TEKİN
Mustafa TAŞDEMİR
Emine ALP MEŞE

Ünvanı

Yönetim Kurulu Başkanı
Yönetim Kurulu Başkan Vekili
Yönetim Kurulu Üyesi
Yönetim Kurulu Üyesi
Yönetim Kurulu Üyesi

Şirketi temsil ve ilzama yönetim kurulu üyeleri herhangi ikisinin müşterek imzası ile yetkili kılınmışlardır.

b) Şirketin Üst Düzey Yöneticileri:

Şirket, **04.02.2019** tarih ve **9759** sayılı Türkiye Ticaret Sicili Gazetesinde tescil ve ilan edilmesi ile birlikte faaliyetlerine başlamış, üst düzey yönetici olarak **Mehmet Ali KILIÇKAYA** genel müdür unvanı ile atanmıştır. Ayrıca şirkette 22.09.2020 tarihinde göreve başlayan Üstün Murat YILDIZ, 06.01.2020 tarihinde göreve başlayan Bilal DEMİRLER ve 27.12.2019 tarihinde göreve başlayan Dinçer ÇETİNTAŞ İcra Kurulu Üyesi olarak görev yapmaktadır.

c) Personel Sayısı:

Şirketin **31.12.2020** tarihi itibarıyla çalışan personel sayısı **69 kişi**'dir.

2- YÖNETİM ORGANI ÜYELERİ İLE ÜST DÜZEY YÖNETİCİLERE SAĞLANAN MALİ HAKLAR

2020 yılında şirket yönetim organı ve üst düzey yöneticilere sağlanan huzur hakkı, ücret, prim, ikramiye, kâr payı gibi mali menfaatlerin toplam tutarları aşağıdaki gibidir. 663 sayılı Kanun Hükmünde Kararnamenin Ek 2 nci maddesinin (9) uncu fıkrası uyarınca; Yönetim kurulunda görev alanlara 22/1/1990 tarihli ve 399 sayılı Kanun Hükmünde Kararnamenin 34 üncü maddesine göre kamu iktisadi teşebbüsleri yönetim kurulu başkan ve üyelerine ödenen tutarda ödeme yapılmaktadır. Bu kapsamda; 2020 yılında toplam 306.230,36 ₺ tutarında ödeme yapılmıştır. Yıl içinde Üst Düzey Yöneticilere ödenen ücret toplamı ise 2.087.770,41 ₺ olarak gerçekleşmiştir.

3- ŞİRKET FAALİYETLERİNE İLİŞKİN ÖNEMLİ GELİŞMELER**a) Şirketin ilgili hesap döneminde yapmış olduğu faaliyetlere ilişkin bilgiler:**

Üsküdar Belediyesi tarafından kullanım hakkı Sağlık Bakanlığına devredilmiş olan Ünalın Mah. Soyak Camii Sok. No:10 Ünalın / Üsküdar adresindeki Erenköy Fizik Tedavi Merkezi Ünalın Şubesinin 1. katının, 2. Katının, bodrum katının ve zemin katın bir bölümünün kullanım hakkı 2020 yılı içerisinde Bakanlık tarafından Şirketimize devredilmiştir. Mülkün kullanıma hazır hale getirilmesi ile ilgili yapım ve tefrişat işlemlerine başlanmıştır. Mevcut durumda ofis kullanılmaya başlanmış ve kalan tefrişat eksikliklerinin giderilmesine çalışılmaktadır. Ofisin kullanıma hazır hale getirilmesi için 2020 yılında toplam 3.932.255 ₺ harcama yapılmıştır. 2021 yılı içerisinde de ofis kurulumu için yaklaşık 3 milyon ₺ harcama yapılması öngörülmektedir. Şirketimiz Ankara Merkez yerleşkesi ise Sağlık Bakanlığı'nın 8. Katı içerisinde yer almaktadır.

Covid 19 Pandemi sürecinde USHAŞ, finansal gücü, özel sektör dinamizmi ve hızlı karar alma prosedürü sayesinde standart bürokratik satın alma süreci yerine kişisel koruyucu ekipmanların doğrudan satın alma yoluyla temininde önemli rol oynamıştır. USHAŞ, kişisel koruyucu ekipmanların piyasada yetkili alıcısı ve dağıtıcısı olarak kişisel koruyucu ekipmanların günlük arzını artırmış ve buna bağlı olarak fiyatların düşmesine katkı sağlamıştır. Satın alma garantisi vererek sektörü yeni yatırımlara ve daha yüksek üretim kapasitesi kullanımına teşvik etmiştir. Tedarik zincirini güvence

altına alarak sürekli üretime yardımcı olmak için üreticilere hammadde sağlamıştır. Kalite güvencesi açısından USHAŞ, Türkiye'de kişisel koruyucu ekipmanların piyasa gözetiminden sorumlu otorite olan Aile, Çalışma ve Sosyal Hizmetler Bakanlığı ve sertifikasyon için bağımsız ve akredite bir kuruluş olan Universal Laboratories ile işbirliği yapmıştır. USHAŞ, cerrahi maske üreticileri ve yetkili satıcıları ile 248 sözleşme imzalayarak 10 Mart - 20 Nisan 2020 tarihleri arasında 1 milyon adetlik günlük dağıtımını 25 milyon adete çıkarmıştır. Pandeminin süresince USHAŞ, Sağlık Bakanlığına bağlı Kamu Hastaneleri, Üniversite Hastaneleri ve Özel Hastaneler başta olmak üzere toplamda;

- 375.800.278 adet 3 Katlı Cerrahi Maske,
- 15.876.308 adet FFP2/N95 Maske,
- 6.504.801 adet Koruyucu Tulum,
- 2.084.044 adet Koruyucu Gözlük,
- 861.157 adet Önlük,
- 104.613.047 adet Muayene Eldiveninin teslimat ve dağıtımını gerçekleştirmiştir.

USHAŞ, koruyucu ekipman temini ile ilgili aktif rolünün yanında Covid 19 tanı kiti ve ventilatör ticaretinde de önemli bir rol üstlenmiştir. Bakanlığımız Halk Sağlığı Genel Müdürlüğü, Mikrobiyoloji Referans Laboratuvarları ve Biyolojik Ürünler Daire Başkanlığı ile Bioeksen Ar-Ge Teknolojileri Ltd. Şti.'den araştırmacılar, SARS-CoV-2'nin moleküler testi için WHO tarafından 17 Ocak 2020'de yayınlanan bir referans protokole dayanarak iki farklı kit geliştirmiştir. Ürünün üretim ve ticarileştirme hakları yalnızca şirketimize aittir. 2020 yılı içerisinde ülkemizde yaklaşık 5 milyon kit testi teslim edilmiş, yurtdışında ise 20'den fazla ülkeye 2 milyondan fazla kit testi satılmıştır.

Biosys Biyomedikal Mühendislik Sanayi ve Ticaret A.Ş. tarafından geliştirilen, fikri ve sınai, mülkiyet hakları Türkiye Sağlık Enstitüleri Başkanlığı'na ait olan %100 yerli ve milli Biyovent marka orta seviye yoğun bakım tipi mekanik ventilatörün üretim ve ticarileştirme hakları şirketimize devredilmiş ve şirketimiz tarafından sırasıyla beş bin adet cihaz Arçelik ve beş bin adet cihaz Aselsan fabrikalarında ürettirilmiştir. Bu kapsamda şirketimizce; Türkiye'de yaklaşık 4.000 Ventilatör teslim edilmiş, yaklaşık 5.000 Ventilatör de 20'den fazla ülkeye ihraç edilmiştir.

Şirketimiz, gerçekleştirdiği tüm bu ticari faaliyetler sonucunda 2.080.387.585,63 ₺ tutarlı net satış gerçekleştirmiş ve yaklaşık 398.878.341,33 ₺ faaliyet kârı elde etmiştir. Söz konusu ticari faaliyetlerin 2021 yılı içerisinde özellikle yerli Covid 19 aşularının ihracatı aşamasında da devam edeceği öngörülmektedir. Bu kapsamda elde edilen net kârın stok ve yatırım harcamalarında kullanılmak üzere işletme sermayesinde tutulmasının yeni kurulmuş olan Şirketimiz faaliyetlerinin daha etkin bir şekilde yürütülmesine katkı sağlayacağı mütalaa edilmektedir.

Gerçekleştirilen ticari faaliyetlerin yanı sıra, Sağlık Turizm Portalının kurulması ile ilgili çalışmalar, Sağlık Turizmi Kurum Derecelendirme ve Değerlendirme çalışmaları, USHAŞ & TÜSKA İş Birliği görüşmeleri, TMC ve THC tanıtım ve pazarlama faaliyetleri, Yurtdışı Temsilciliklerin yapılandırılması çalışmaları, G2G müzakereleri ve anlaşmaları, Uluslararası Kuruluşlar ile işbirliği çalışmaları, Dışişleri Bakanlığı ve İçişleri Bakanlığı Göç İdaresi Genel Müdürlüğü ile Sağlık Vizesi uygulamasının iyileştirilmesine yönelik çalışmalar, İGA-İstanbul Havalimanı İşbirliği kapsamında

Sağlık turistleri VIP karşılama hizmeti ve STP ile entegrasyonu çalışmaları, Türkiye Sigorta ile İşbirliği kapsamında Komplikasyon Sigortası, Malpraktis Sigortası ve Seyahat Sağlığı Sigortası görüşmeleri şirketimiz tarafından sürdürülmektedir.

Şirketimiz 2020 yılı içerisinde Birleşmiş Milletler Kalkınma Programı'nın (UNDP) İstanbul Uluslararası Özel Sektör ve Kalkınma Merkezi (IICPSD) ile COVID-19 salgını nedeniyle ihtiyaç duyulan kişisel koruyucu ekipman (PPE) talebini uluslararası ölçekte işbirliği ile karşılamak amacıyla bir mutabakat zaptı imzalamıştır. Mutabakat zaptı ile paydaşlar arasında kapasite oluşturma, iletişimin artırılması ve kişisel koruyucu ekipman arz zinciri know-how'larının az gelişmiş ve gelişmekte olan ülkelerle paylaşılması hedeflenmiş ve Şirketimizin örnek gösterildiği bir faaliyet raporu yayımlanmıştır. Söz konusu faaliyet raporu, 2020 yılı faaliyet raporu ekinde belirtilmiştir.

Covid-19 salgını ile beraber kritik hale gelen medikal cihazlar, ilaçlar ve kişisel koruyucu ekipmanların üretimi ve dağıtımı konusunda üye ülkeler arasındaki iş birliğinin artırılması amacı ile 2020 yılı içerisinde Türk Keneşi'nin "Tedarik Zinciri Grubu" toplantısı gerçekleştirilmiştir. Toplantıda USHAŞ olarak pandemi döneminde gerçekleştirilen çalışmalar ve UNDP tarafından dünyaya örnek gösterilen USHAŞ kişisel koruyucu ekipman çalışması raporu ele alınmıştır. Üye ülkelerin resmi temsilcilerinin ve özel şirket temsilcilerinin katılımıyla gerçekleşen toplantıda üye ülkelerin ortak kararı ile Şirketimiz Genel Müdürü ve Yönetim Kurulu Başkan Vekili Mehmet Ali KILIÇKAYA, Türk Konseyi Tedarik Zinciri Grubunun başkanı olarak seçilmiştir.

2020 yılı içerisinde uluslararası işbirliği kurulmasına yönelik çalışmalar kapsamında Burkina Faso Büyükelçisi Sn. Brahim Sere ile 17 Eylül 2020 tarihinde, Kuveyt Sağlık Bakanlığı yetkilileri ve Panama Büyükelçisi Sn. Mariela Sagel ile 20 Ekim 2020 tarihinde, Burundi Büyükelçisi Sn. Gérard Ntahorwaroye Bikebako ile 5 Kasım 2020 tarihinde, Cibuti Sağlık Bakanı Sn. Mohamed Warsama Dirieh ile 14 Aralık 2020 tarihinde, Dünya Sağlık Örgütü Türkiye Temsilcisi ile 16 Aralık 2020 tarihinde, Sudan Büyükelçisi Sn. Adil İbrahim MUSTAFA ve heyeti ile 25 Aralık 2020 tarihinde işbirliği görüşmeleri yapılmıştır. Gürcistan Sağlık Bakanlığı ile 8 Aralık 2020 tarihinde düzenlenen toplantıya şirketimiz Yönetim Kurulu Başkanı Salih Kenan Şahin, Genel Müdürü Mehmet Ali Kılıçkaya ve Gürcistan'ın Ankara Büyükelçisi George Janjgava fiziken; Gürcistan Sağlık Bakan Yardımcısı Giorgi Tsotskolauri da video konferans üzerinden katılım sağlamış ve toplantı esnasında USHAŞ ile Gürcistan Sağlık Bakanlığı arasında işbirliği protokolü imzalanmıştır.

b) Şirketin iç kontrol sistemi ve iç denetim faaliyetleri hakkında bilgiler ile yönetim organının bu konudaki görüşü:

2020 yılında iç kontrol sistemi ve iç denetim ile ilgili çalışma başlatılmış olup, 2021 yılı içerisinde Şirket bünyesinde bir İç Denetçi görevlendirilerek iç kontrol sisteminin kurulması planlanmaktadır.

c) Şirketin doğrudan veya dolaylı iştirakleri ve pay oranlarına ilişkin bilgiler:

Şirketin doğrudan bağlı ortaklığı SADES Sağlık ve Sağlık Turizmi Destek Hizmetleri A.Ş.'dir. 2020 yılında kurulan Şirketin sermayesi 500.000,00 ₺ olup tamamı USHAŞ Uluslararası Sağlık Hizmetleri A.Ş.'ne aittir.

d) Hesap dönemi içerisinde yapılan özel denetime ve kamu denetimine ilişkin açıklamalar:

Şirketimiz 2020 yılında kamu denetimine tabi tutulmuş olup, T.C. Sayıştay Başkanlığı'nın ilgili denetim ekibi çalışmalarına devam etmektedir. Ayrıca Kurumlar Vergisi matrahı ve eki ile mali tablolarının denetimi KPMG tarafından gerçekleştirilmektedir.

e) Şirket aleyhine açılan ve şirketin mali durumunu ve faaliyetlerini etkileyebilecek nitelikteki davalar ve olası sonuçları hakkında bilgiler:

Şirketimiz aleyhine Çam Konfeksiyon ve San. Tic. Ltd. Şti. tarafından 30/12/2020 tarihinde Ankara 14. Asliye Ticaret Mahkemesi nezdinde ticari satımdan kaynaklı alacak davası açılmıştır. Davacı fazlaya ilişkin hakları saklı kalmak kaydıyla 10.000 ₺ bedel üzerinden belirsiz alacağını talep etmiştir. Dilekçeler safahatı tamamlanan davanın öncelikle hukuki yarar yokluğundan usulden reddi; işin esasına girilmesi halinde ise cevaplarımız ve itirazlarımız dikkate alınarak davanın esastan reddi talep edilmiştir. Davanın lehimize sonuçlanması ve dolayısıyla şirketin mali durumunun etkilenmemesi öngörülmektedir.

f) Mevzuat hükümlerine aykırı uygulamalar nedeniyle şirket ve yönetim organı üyeleri hakkında uygulanan idari veya adli yaptırımlara ilişkin açıklamalar:

2020 yılı Şirket faaliyetleri kapsamında mevzuat hükümlerine aykırı bir uygulama ve buna ilişkin uygulanmış adli veya idari bir yaptırım yoktur.

g) Geçmiş dönemlerde belirlenen hedeflere ulaşıp ulaşılamadığı, genel kurul kararlarının yerine getirilip getirilmediği, hedeflere ulaşamamışsa veya kararlar yerine getirilmemişse gerekçelerine ilişkin bilgiler ve değerlendirmeler:

Şirket Covid 19 pandemi sürecinin de etkisi ile geçmiş dönemlerde belirlenen hedeflerin çok üzerinde bir ticari potansiyele sahip olmuştur. İlerleyen süreçte yerli aşının ihracatı işlemleri ile bu potansiyelin daha da geliştirileceği beklenmektedir. Diğer taraftan sağlık turizmi ile ilgili hedeflerin yine Covid 19 pandemi sürecinin de etkisi ile gerisinde kalınmıştır. İlerleyen süreçte sağlık turizmi ile ilgili hedeflere de ulaşılması için azami gayret gösterilmektedir.

h) Yıl içerisinde olağanüstü genel kurul toplantısı yapılmışsa, toplantının tarihi, toplantıda alınan kararlar ve buna ilişkin yapılan işlemlerde dâhil olmak üzere olağanüstü genel kurula ilişkin bilgiler:

09.06.2020 tarihinde Olağanüstü Genel Kurul Toplantısı yapılmıştır. Toplantıda, Yönetim Kurulu Başkanı Cevat ŞENGÜL'ün Yönetim Kurulundan istifası kabul edilmiştir.

28.07.2020 tarihinde Olağanüstü Genel Kurul Toplantısı yapılmıştır. Toplantıda, Salih Kenan Şahin Yönetim Kurulu Üyesi seçilmiş, Ahmet TEKİN'in Yönetim Kurulu Başkanlığı görevi sona ererek temsile yetkili olarak seçilmiş, yerine Salih Kenan ŞAHİN Yönetim Kurulu Başkanı seçilmiştir. Belirtilen kişiler 31.01.2022 tarihine kadar görev yapmak üzere seçilmiştir.

i) Şirketin yıl içinde yapmış olduğu bağış ve yardımlar ile sosyal sorumluluk projeleri çerçevesinde yapılan harcamalara ilişkin bilgiler:

Şirketimiz tarafından 2020 yılında ihtiyacı olan kamu kurumlarına, üniversitelere ve hastanelere; içeriği koruyucu ekipman, sarf malzeme, tıbbi cihaz ve ilaçtan oluşan toplam 14.533.514,40 ₺ değerinde bağış yapılmıştır.

4-FİNANSAL DURUM

Şirket 04.02.2019 tarihi itibarıyla faaliyete başlamış olup, 31.12.2020 sonu itibarıyla 2.080.387.585,63 ₺ net satışı mevcuttur. Brüt kârı 499.897.187,58 ₺ olmakla birlikte, 2020 yılında 398.878.341,33 ₺ faaliyet karı mevcuttur. Net satışlarının tamamına yakını koruyucu ekipman, ilaç, tıbbi cihaz ve sarf malzeme satış gelirlerinden oluşmaktadır.

Şirket, 2020 yılında 782.545,01 ₺ faiz geliri elde ederken, kurdaki dalgalanmalardan kaynaklı 4.167.821,80 ₺ kur farkı zararı oluşmuştur.

Şirketin 2020 yılı faaliyet dönemi 307.984.711,23 ₺ net kar ile sonuçlanmış olup, 87.107.203,80 ₺ Kurumlar vergisi ödemiştir.

Şirketin 2019 ve 2020 yılı mali göstergeleri üzerinden yapılan temel analizler aşağıdaki gibidir.

Finansal Kaldıraç Oranı

Şirket'in 2019 ve 2020 yıllarına ilişkin varlıklarının ne kadarını yabancı kaynaklar ile finanse ettiğini gösteren finansal kaldıraç oranı aşağıdaki gibidir.

Varlık Türü	2019	2020
Yabancı Kaynak	1.647.555,06	173.077.513,89
Aktif (Varlıklar)	9.951.990,83	489.366.660,89
Finansal Kaldıraç Oranı	17%	36%

Karlılık Analizi

Şirket'in 2019 ve 2020 yıllarına ilişkin satış bilgileri ve bu satışlara ilişkin maliyet tablosu aşağıdaki gibidir.

Gelir Tablosu Kalemleri	2019	2020
Hasılat	2.341.724,32	2.206.218.810,23

Satışların Maliyeti (-)	1.724.859,43	1.580.490.398,05
BRÜT KAR/ZARAR	616.864,89	499.897.187,58
Karlılık (%)	26%	24%

Gider Dağılımı

Şirketin 2019 ve 2020 yıllarına ilişkin olarak pazarlama satış dağıtım gideri, genel yönetim gideri ve finansman gideri aşağıdaki gibidir:

Gider Türü	2019	2020
Pazarlama Satış Dağıtım Giderleri	8.693,60	76.024.879,55
Genel yönetim giderleri	2.988.372,76	24.993.966,70
Finansman Gideri	0,00	0,00
Toplam	2.997.066,36	101.018.846,25

EBITDA Analizi

Şirketin 2019 ve 2020 yıllarına ilişkin faiz, amortisman gideri ve vergi öncesi karını gösteren EBITDA (FAVÖK) tutarlarına ilişkin hesaplama tablosu aşağıdaki gibidir

EBITDA	2019	2020
Net Satışlar	2.341.724,32	2.080.387.585,63
Satışların Maliyeti (-)	1.724.859,43	1.580.490.398,05
Pazarlama, Satış Dağıtım Giderleri(-)	8.693,60	76.024.879,55
Genel Yönetim Giderleri (-)	2.988.372,76	24.993.966,70
Amortisman Gideri	0,00	2.870.138,89
EBITDA	-2.380.201,47	396.008.202,44

4.1. VUK'a Göre Hazırlanmış Finansal Tablolar:

Şirketin Muhasebe Sistemi Uygulama Genel Tebliğine göre hazırlanmış **2020** yılına ilişkin karşılaştırmalı finansal tabloları aşağıdaki gibidir.

a) Bilanço

	2019	2020
	Önceki Dönem	Cari Dönem
AKTİF		
DÖNEN VARLIKLAR TOPLAMI	9.848.652,97	465.690.846,60
A HAZIR DEĞERLER	8.408.289,44	222.110.635,21
01. Kasa	11,02	2.697,44
02. Alınan çekler	0,00	0,00
03. Bankalar	8.408.278,42	222.079.922,77
04. Verilen Çekler ve Ödeme Emirleri (-)	0,00	0,00
05. Diğer hazır değerler	0,00	28.015,00
C TİCARİ ALACAKLAR	1.031.873,47	173.704.933,24
01. Alıcılar	1.031.873,47	173.664.114,67
02. Alacak Senetleri	0,00	0,00
03. Alacak Senetleri Reeskontu (-)	0,00	0,00
04. Verilen Depozito ve Teminatlar	0,00	40.818,57

05. Kazanılmamış Finansal Kiralama Faiz Gelirleri(-)	0,00	0,00
06. Diğer Ticari Alacaklar	0,00	0,00
07. Şüpheli Ticari Alacaklar	0,00	0,00
08. Şüpheli Ticari Alacaklar Karşılığı(-)	0,00	0,00
D DİĞER ALACAKLAR	0,00	24.002,70
01. Ortaklardan Alacaklar	0,00	0,00
02. İştiraklerden Alacaklar	0,00	0,00
03. Bağlı Ortaklıklardan Alacaklar	0,00	6.377,66
04. Personelden Alacaklar	0,00	0,00
05. Diğer Çeşitli Alacaklar	0,00	17.625,04
06. Diğer Alacak Senetleri Reeskontu (-)	0,00	0,00
07. Şüpheli Diğer Alacaklar	0,00	0,00
08. Şüpheli Diğer Alacaklar Karşılığı (-)	0,00	0,00
E STOKLAR	94.808,03	67.067.298,66
01. İlk Madde ve Malzeme	0,00	0,00
02. Yarı Mamuller - Üretim	0,00	0,00
03. Mamuller	0,00	0,00
04. Ticari Mallar	51.486,00	66.350.924,10
05. Diğer Stoklar	0,00	0,00
06. Stok Değer Düşüklüğü Karşılığı(-)	0,00	0,00
07. Verilen Sipariş Avansları	43.322,03	716.374,56
G GELECEK AYLARA AİT GİDERLER VE GELİR TAHAKKUKLARI	0,00	5.424,06
01. Gelecek Aylara Ait Giderler	0,00	0,00
02. Gelir Tahakkukları	0,00	5.424,06
H DİĞER DÖNEN VARLIKLAR	313.682,03	2.778.552,73
01. Devreden KDV	162.088,18	2.621.685,10
02. İndirilecek Katma Değer Vergisi	0,00	0,00
03. Diğer Katma Değer vergisi	0,00	0,00
04. Peşin Ödenen Vergiler ve Fonlar	118.757,32	0,00
05. İş Avansları	32.836,53	156.867,63
06. Personel Avansları	0,00	0,00
07. Sayım ve Tesellüm Noksanları	0,00	0,00
08. Diğer Çeşitli Dönen Varlıklar	0,00	0,00
09. Diğer Dönen Varlıklar Karşılığı(-)	0,00	0,00
DURAN VARLIKLAR TOPLAMI	103.337,86	23.675.814,29
C MALİ DURAN VARLIKLAR	0,00	125.000,00
01. Bağlı Menkul Kıymetler	0,00	0,00
02. Bağlı Menkul Kıymetler Değer Düşüklüğü Karşılığı (-)	0,00	0,00
03. İştirakler	0,00	0,00
04. İştiraklere Sermaye Taahhütleri (-)	0,00	0,00
05. İştirakler Sermaye Payları Değer Düşüklüğü Karşılığı	0,00	0,00
06. Bağlı Ortaklıklar	0,00	500.000,00
07. Bağlı Ortaklıklara Sermaye Taahhütleri (-)	0,00	-375.000,00

08. Bağlı Ortaklıklar Sermaye Payları değer Düşüklüğü Karşılığı (-)	0,00	0,00
09. Diğer Mali Duran Varlıklar	0,00	0,00
10. Diğer Mali Duran Varlıklar Karşılığı	0,00	0,00
D MADDİ DURAN VARLIKLAR	96.361,49	2.234.871,29
01. Arazi ve Arsalar	0,00	0,00
02. Yer Altı ve Yer Üstü Düzenleri	0,00	0,00
03. Binalar	0,00	0,00
04. Tesis, Makine ve Cihazlar	0,00	0,00
05. Taşıtlar	0,00	830.924,76
06. Demirbaşlar	96.361,49	1.716.483,85
07. Diğer Maddi Duran Varlıklar	0,00	0,00
08. Birikmiş Amortismanlar (-)	0,00	-312.537,32
09. Yapılmakta Olan Yatırımlar	0,00	0,00
10. Verilen Avanslar	0,00	0,00
E MADDİ OLMAYAN DURAN VARLIKLAR	6.976,37	4.643.409,47
01. Haklar	6.976,37	3.142.076,90
02. Şerefiye	0,00	0,00
03. Kuruluş ve Örgütlenme Giderleri	0,00	0,00
04. Araştırma ve Geliştirme Giderleri	0,00	0,00
05. Özel Maliyetler	0,00	3.932.255,42
06. Diğer Maddi Olmayan Duran Varlıklar	0,00	126.678,72
07. Birikmiş Amortismanlar(-)	0,00	-2.557.601,57
08. Verilen Avanslar	0,00	0,00
G GELECEK YILLARA AİT GİDERLER VE GELİR TAHAKKUKLARI	0,00	16.672.533,53
01. Gelecek Yıllara ait Giderler	0,00	16.672.533,53
02. Gelir Tahakkukları	0,00	0,00
AKTİF TOPLAMI	9.951.990,83	489.366.660,89

PASİF	2019 Önceki Dönem	2020 Cari Dönem
KISA VADELİ YABANCI KAYNAKLAR TOPLAMI	1.647.555,06	173.077.513,89
A MALİ BORÇLAR	0,00	17.216,74
01. Banka Kredileri	0,00	0,00
02. Finansal Kiralama İşlemlerinden Borçlar	0,00	0,00
03. Ertelenmiş Finansal Kiralama Borçlanma Maliyetleri(-)	0,00	0,00
04. Uzun Vadeli Kredilerin Anapara Taksitleri ve Faizleri	0,00	0,00
05. Tahvil Anapara Borç, Taksit ve Faizleri	0,00	0,00
06. Çıkarılmış Bonolar ve Senetler	0,00	0,00
07. Çıkarılmış Diğer Menkul Kıymetler	0,00	0,00

08. Menkul Kıymetler İhraç Farkı (-)	0,00	0,00
09. Diğer Mali Borçlar	0,00	17.216,74
B TİCARİ BORÇLAR	884.515,81	136.795.047,74
01. Satıcılar	855.231,26	136.795.047,74
02. Borç Senetleri	0,00	0,00
03. Borç Senetleri Reeskontu (-)	0,00	0,00
04. Alınan Depozito ve Teminatlar	0,00	0,00
05. Diğer Ticari Borçlar	29.284,55	0,00
C DİĞER BORÇLAR	215.926,63	630.181,02
01. Ortaklara Borçlar	0,00	0,00
02. İştiraklere Borçlar	0,00	0,00
03. Bağlı Ortaklıklara Borçlar	0,00	0,00
04. Personele Borçlar	212.891,69	608.538,31
05. Diğer Çeşitli Borçlar	3.034,94	21.642,71
06. Diğer Borç Senetleri Reeskontu (-)	0,00	0,00
D ALINAN AVANSLAR	174.764,38	3.920.426,62
01. Alınan Sipariş Avansları	174.764,38	3.920.426,62
02. Alınan Diğer Avanslar	0,00	0,00
E YILLARA YAYGIN İNŞAAT VE ONARIM HAKEDİŞLERİ	0,00	0,00
01. Yıllara Yaygın İnşaat ve Onarım Hakediş Bedelleri	0,00	0,00
02. Yıllara Yaygın İnşaat Enflasyon Düzeltme Hesabı	0,00	0,00
F ÖDENECEK VERGİ VE DİĞER YÜKÜMLÜLÜKLER	260.937,99	798.715,21
01. Ödenecek Vergi ve Fonlar	174.277,92	418.188,32
02. Ödenecek Sosyal Güvenlik Kesintileri	86.660,07	372.888,84
03. Vadesi Geçmiş Ertelenmiş Veya Taksitlendirilmiş Vergi ve Diğer Yükümlülük	0,00	0,00
04. Ödenecek Diğer Yükümlülükler	0,00	7.638,05
G BORÇ VE GİDER KARŞILIKLARI	0,00	7.377.205,75
01. Dönem Karı Vergi ve Diğer Yasal Yükümlülük Karşılıkları	0,00	87.107.203,80
02. Dönem Karının Peşin Ödenen Vergi ve Diğer Yükümlülükleri(-)	0,00	-79.729.998,05
03. Kıdem Tazminatı Karşılığı	0,00	0,00
04. Maliyet Giderleri Karşılığı	0,00	0,00
05. Diğer Borç ve Gider Karşılıkları	0,00	0,00
H GELECEK AYLARA AİT GELİRLER VE GİDER TAHAKKUKLARI	111.410,25	23.538.720,81
01. Gelecek Aylara Ait Gelirler	111.410,25	23.122.575,00
02. Gider Tahakkukları	0,00	416.145,81
ÖZKAYNAKLAR TOPLAMI	8.304.435,77	316.289.147,00
A ÖDENMİŞ SERMAYE	10.000.000,00	10.000.000,00
01. Sermaye	10.000.000,00	10.000.000,00
02. Ödenmemiş Sermaye (-)	0,00	0,00
03 Sermaye Düzeltmesi Olumlu Farkları	0,00	0,00

04.Sermaye Düzeltmesi Olumsuz Farkları (-)	0,00	0,00
D GEÇMİŞ YILLAR KARLARI	0,00	0,00
01.Geçmiş Yıl Karları	0,00	0,00
E GEÇMİŞ YILLAR ZARARLARI (-)	0,00	-1.695.564,23
01.Geçmiş Yıl Zararları (-)	0,00	-1.695.564,23
F DÖNEM NET KARI(ZARARI)	-1.695.564,23	307.984.711,23
01. Dönem Net Karı	0,00	307.984.711,23
02. Dönem Net Zararı (-)	-1.695.564,23	0,00
PASİFLER TOPLAMI	9.951.990,83	489.366.660,89

b) Gelir Tablosu

	2019 / Önceki Dönem	2020 / Cari Dönem
A- BRÜT SATIŞLAR	2.341.724,32	2.206.218.810,23
1. Yurtiçi Satışlar	177.032,35	1.838.376.211,76
2. Yurtdışı Satışlar	2.164.217,97	322.183.075,37
4. Diğer Gelirler	474,00	45.659.523,10
B- SATIŞ İNDİRİMLERİ (-)	0,00	125.831.224,60
1. Satıştan İadeler (-)	0,00	105.689.455,50
2. Satış İskontoları (-)	0,00	20.141.769,10
3. Diğer İndirimler (-)	0,00	0,00
C- NET SATIŞLAR	2.341.724,32	2.080.387.585,63
D- SATIŞLARIN MALİYETİ (-)	1.724.859,43	1.580.490.398,05
1. Satılan Mamül Maliyeti (-)	0,00	86.385.625,76
2. Satılan Ticari Mallar Maliyeti (-)	1.535.385,96	1.485.319.656,02
3. Satılan Hizmet Maliyeti (-)	189.473,47	8.785.116,27
BRÜT SATIŞ KARI VEYA ZARARI	616.864,89	499.897.187,58
E- FAALİYET GİDERLERİ (-)	2.997.066,36	101.018.846,25
1. Araştırma ve Geliştirme Giderleri (-)	0,00	0,00
2. Pazarlama, Satış ve Dağıtım Giderleri (-)	8.693,60	76.024.879,55
3. Genel Yönetim Giderleri (-)	2.988.372,76	24.993.966,70
FAALİYET KARI VEYA ZARARI	-2.380.201,47	398.878.341,33
F- DİĞER FAALİYETLERDEN OLAĞAN GELİR VEYA KARLAR	803.988,45	30.404.307,26
1. İştiraklerden Temettü Gelirleri	0,00	0,00
2. Bağlı Ortaklıklardan Temettü Gelirleri	0,00	0,00
3. Faiz Gelirleri	791.715,27	782.545,01
4. Komisyon Gelirleri	0,00	0,00
5. Konusu Kalmayan Karşılıklar	0,00	0,00
6. Menkul Kıymet Satış Karları	0,00	0,00
7. Kambiyo Karları	4.256,59	29.621.762,25
8. Reeskont Faiz Gelirleri	0,00	0,00
9. Enflasyon Düzeltme Karları	0,00	0,00
10. Diğer Olağan Gelir ve Karlar	8.016,59	0,00
G- DİĞER FAALİYETLERDEN OLAĞAN GİDER VE ZARARLAR (-)	123.111,09	33.789.584,05
1. Komisyon Giderleri	0,00	0,00
2. Karşılık Giderleri	0,00	0,00
3. Menkul Kıymet Satış Zararları	0,00	0,00
4. Kambiyo Zararları	123.111,08	33.789.584,05
5. Reeskont Faiz Giderleri	0,00	0,00
6. Enflasyon Düzeltme Zararları	0,00	0,00
7. Diğer Olağan Gider ve Zararlar	0,01	0,00

H- FİNANSMAN GİDERLERİ (-)	0,00	0,00
1. Kısa Vadeli Borçlanma Giderleri (-)	0,00	0,00
2. Uzun Vadeli Borçlanma Giderleri (-)	0,00	0,00
OLAĞAN KAR VEYA ZARAR	-1.699.324,11	395.493.064,54
I- OLAĞANDIŞI GELİR VE KARLAR	11.547,97	116.022,91
1. Önceki Dönem Gelir ve Karları	0,00	0,00
2. Diğer Olağandışı Gelir ve Karlar	11.547,97	116.022,91
J- OLAĞANDIŞI GİDER VE ZARARLAR (-)	7.788,09	517.172,42
1. Çalışmayan Kısım Gider ve Zararları (-)	0,00	0,00
2. Önceki Dönem Gider ve Zararlar (-)	0,00	0,00
3. Diğer Olağandışı Gider ve Zararlar (-)	7.788,09	517.172,42
DÖNEM KARI VEYA ZARARI	-1.695.564,23	395.091.915,03
K- DÖNEM KARI VERGİ VE DİĞER YASAL YÜKÜMLÜLÜK KARŞILIKLARI (-)	0,00	87.107.203,80
DÖNEM NET KARI VEYA ZARARI	-1.695.564,23	307.984.711,23

4.2. Şirketin sermayesinin karşılıksız kalıp kalmadığına veya borca batık olup olmadığına ilişkin tespit ve yönetim organı değerlendirmeleri:

TTK'nun 376'ncı maddesine göre; şirket sermayesi karşılıksız kalmadığı gibi borca batıklık durumu da oluşmamıştır.

4.3. Kar Dağıtım Önerisi:

Şirketin 2020 yılı Faaliyet Dönemi 307.984.711,23 ₺ Net kâr ile sonuçlanmış olup, 2021 yılında planlanan ticari faaliyetler, stok ve yatırım harcamaları çerçevesinde söz konusu tutarın sermayeye eklenmesi uygun görülmektedir.

5- RİSKLER VE YÖNETİM ORGANININ DEĞERLENDİRİLMESİ

a) Varsa şirketin öngörülen risklere karşı uygulayacağı risk yönetimi politikasına ilişkin bilgiler:

Şirketin yatırımlarını özkaynakları ile yapması, yabancı para cinsinden mümkün olduğunca işlem tesis etmemesi ve nakit fazlalıkların ise riski olmayan yatırım araçlarında değerlendirmesi nedenleriyle öngörülen riskleri bulunmamaktadır.

b) Satışlar, verimlilik, gelir yaratma kapasitesi, kârlılık, borç/özkaynak oranı ve benzeri konularda ileriye dönük riskler:

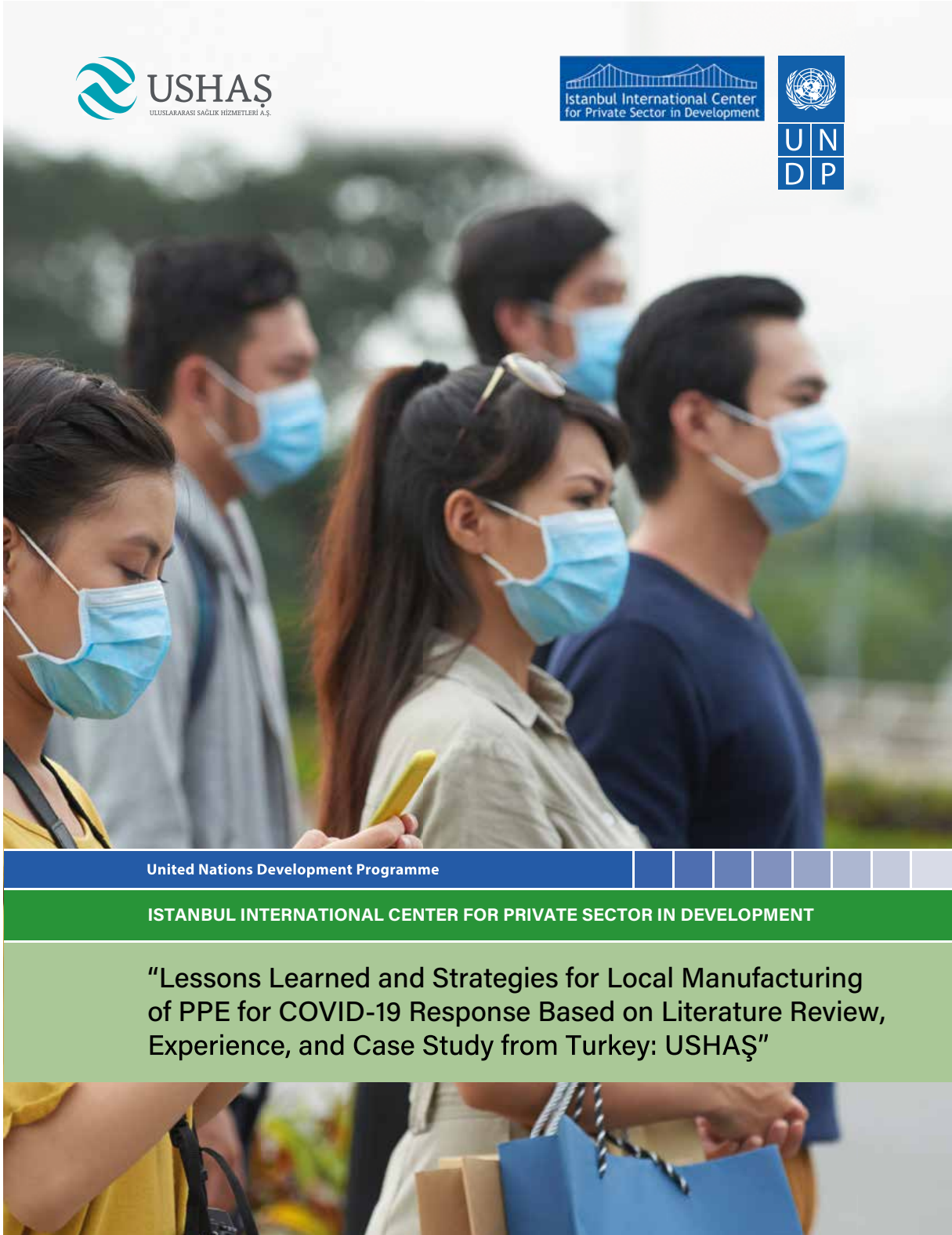
Şirket 2019 yılında faaliyetine başlamış olup, 2020 yılında 2.0780.387.585,63 ₺ hasılat elde etmiş ve yıl sonunu 307.984.711,23 ₺ net kar ile kapatmıştır. Brüt karlılığı %24 civarında olup, mevcut piyasa koşulları dışında öngörülen bir riski mevcut değildir.

6- Diğer Hususlar

a) Faaliyet yılının sona ermesinden sonra şirkette meydana gelen ve ortakların, alacaklıların ve diğer ilgili kişi ve kuruluşların haklarını etkileyebilecek nitelikteki özel önem taşıyan olaylara ilişkin açıklamalar:

Şirketin faaliyet yılı sonrasında meydana gelmiş olup ilişkili tarafların haklarını etkileyecek nitelikte özel önem arz eden bir olay yaşanmamıştır.

Ek: UNDP-USHAŞ Faaliyet Raporu





“Lessons Learned and Strategies for Local Manufacturing of PPE for COVID-19 Response Based on Literature Review, Experience, and Case Study from Turkey: USHAŞ”

“Lessons Learned and Strategies for Local Manufacturing of PPE for COVID-19 Response Based on Literature Review, Experience, and Case Study from Turkey: USHAŞ”

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UNITED NATIONS DEVELOPMENT PROGRAMME
ISTANBUL INTERNATIONAL CENTER FOR PRIVATE SECTOR IN DEVELOPMENT

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ABBREVIATIONS

AAMI	- Association for the Advancement of Medical Instrumentation
ADB	- Asian Development Bank
ANSI	- American National Standards Institute
ASTM	- American Society for Testing and Materials
AQL	- Acceptable quality limit
CapEx	- Capital Expenditure
CDC	- The Centers for Disease Control and Prevention
CNAS	- The China National Accreditation Service for Conformity Assessment
EA	- European Accreditation
EBIT	- Earnings Before Interest and Tax
EEC	- European Economic Community
EMS	- Environmental Management Systems
ESG	- Environmental, Social, Governance
EU	- European Union
EUA	- Emergency Use Authorization
FDA	- The US Food and Drug Administration
GMP	- Good Manufacturing Practices
GOST	- Russia's State Standards
IFC	- International Finance Corporation
IICPSD	- Istanbul International Center for Private Sector in Development
ILO	- International Labour Organization
ISO	- International Organization for Standardization
OSH	- Occupational Safety and Health
PPE	- Personal Protective Equipment
SMS	- Spunbond Meltblown Spunbond
SDGs	- Sustainable Development Goals
USHAŞ	- Uluslararası Sağlık Hizmetleri A.Ş.
WHO	- World Health Organization
WTI	- World Trade Institute

FOREWORD


COVID-19, which had an unprecedented impact on the world, once again demonstrated the importance of personal protective equipment, especially for healthcare workers at the forefront. However, with the emergence of COVID-19 turning into a global epidemic, international demand for these equipment and devices has increased exponentially. Due to the fact that the limited number of personal protective equipment produced for use in the health sector throughout the world has not been able to meet this exceptional global and general demand in the utility of such, the international community has struggled with the epidemic and at the same time with stocking, export bans and also with problems such as seizure.

Personal protective equipment is produced in two categories, for medical and non-medical uses. Furthermore, not all personal protective equipments provide the same level of protection. In order to meet the increasing demand with the global COVID-19 pandemic, many sectors and industries have repurposed their employees and their manufacturing for the production of personal protective equipments. However, when this situation did not come with regulations for quality standards, it led to the spread of substandard and poor quality of personal protective equipments. Substandard and poor quality of personal protective equipments circulating in the market poses a great health risk due to the insufficient or at times no protection. For this reason, these products threaten the public health and safety of healthcare workers and citizens and undermine the effect of public health measures in implementation. In this environment, the importance of quality personal protection products has increased once again and countries have turned to products with international quality standards and that successfully met the required regulations while supplying personal protective equipment.

In order to meet the increasing demand for quality and effective personal protective equipment and devices all over the world, many international organizations, especially the World Health Organization, prepared guidelines and standards for the quality of these products on the basis of their own work areas. To be able to ensure the sustainability of these products, countries have adjusted their domestic industry and production capacity to meet this increasing national and international demand.

In this global environment, new partnerships and cooperation is of vital importance. With this in mind, our country, which has been strengthening its health care infrastructure that has highlighted itself in the international community for the last few years, established an international company which is affiliated to Ministry of Health, Uluslararası Sağlık Hizmetleri A.Ş. (USHAŞ International Health Services Inc.) in 2019. USHAŞ carries out duties such as supplying pharmaceuticals, medical devices and equipments as well as supporting and coordinating activities related to health tourism. Since the onset of the pandemic USHAŞ that serves for the public interest with the mindset of a private enterprise and tools, has played a critical role in supplying personal protective equipment firstly for the healthcare workers and citizens across Turkey, and contributed significantly to the international community in fight against COVID-19 pandemic. The role of USHAŞ as a supplier of personal protection products within the scope of fight against COVID-19, and the success of its rapid supply and distribution network, led to the increase in national production and a decrease in prices. Moreover, USHAŞ's support to national ventilator diagnostics in terms of finance, production capacity and exportation was deemed an exemplary success by United Nations Development Programme (UNDP).

In order to meet the national and global personal protective equipments demand, to develop production capacity in international standards, and to carry our national experience abroad, Turkey has pioneered a very important international partnership in the production of personal protective equipment and, a Memorandum of Understanding (MoU) was signed on 17 June 2020 between USHAŞ and UNDP IICPSD which is established to strengthen the private sector in development. With MoU, it is aimed to increase local capacity and develop joint capacity in the field of personal protective equipments production. As an output of the MoU, a report has been developed as a one-stop-shop solution in a short time which consists of all the information required to produce personal protective equipment for both domestic and foreign manufacturers is collected under a single roof. The prepared report summarizes all stages of the supply chain, especially the raw material supply required for personal protective equipment, production lines and certification. I have no doubt that, the technical information in the report will assist the least developed and developing countries in establishment of their own supply chain and overcome the pandemic more midly.

Our country has already shown an important example of international solidarity by sending quality personal protective equipments to 159 countries and 9 international organizations. I believe that this report, which blends the lessons learned and strategies required for the production of personal protective equipments and devices and contains all the vital information for that, will make great contributions to the ease the bottlenecks in the international supply chain and the develop local capacities which manufactures at international quality standards. I think that this collaboration of USHAŞ and UNDP IICPSD will serve as a bridging the gaps in global personal protective equipments supply and meeting international quality standards and this cooperation will be an example to the international community in combining the tools of the economy sector with the needs of the health sector. I wish that this report will be beneficial to everyone, and that the technical information in the report will contribute to emerging markets to establish their own personal protective equipment supply chains and to overcome the challenges of pandemic process more easily.

Prof. Dr. Emine Alp Meşe
Deputy Minister of Republic of Turkey Ministry of Health
Member of the Board of USHAŞ

FOREWORD

FOREWORD



The Covid-19 outbreak, which started in Wuhan, China at the end of 2019, surrounded the world, after which WHO declared it a pandemic on March 11, 2020. At the beginning of March, when the pandemic was declared, there was a shortage of protective equipment all over the world. For this reason, the prices of protective materials had increased speculatively compared to before the pandemic. Around the same dates, Turkey had also started to have problems in accessing supplies of masks and protective equipment. Raw material costs also increased due to increased demand. Production capacities were insufficient to meet the domestic market demand. In such a period of extraordinary conditions, USHAŞ was assigned by the Ministry of Health to supply protective materials and was determined as the only supplier. With its unique dynamic structure, USHAŞ has developed a fast and alternative procurement model on behalf of the public, controlled the supply and prices of raw materials by using its sole purchaser and distributor authority, increased daily supply, and reduced prices. USHAŞ has managed an intensive operational process through the supply and logistics network that it had created. The procurement duty of USHAŞ that started with the task of meeting the demand of public hospitals, has, after some point, expanded to the point where it can distribute free of charge to university hospitals, private hospitals, public institutions and organizations, industrial establishments and the public.

During this period, USHAŞ played a key role in the production, financing, distribution, and export of the domestic and national PCR diagnostic test, which is an important instrument in combating the COVID-19 outbreak. By supplying these tests to the Ministry of Health at a price much lower than global prices, it contributed to public financing and obtained foreign currency input with its exports. On this occasion, it also contributed to the growth of the manufacturer at the start-up level. The same model was utilized for the production of local and national respiratory machines, which are another important instrument for combatting the pandemic. USHAŞ has financed Turkey's first local and national respiratory machines under its purchase guarantee. The foreign exchange that was obtained through exports while the devices were supplied to public hospitals at the price of their cost of production, has been an important revenue item for USHAŞ and has also contributed to the growth of the start-up-level intellectual property owner firms.

In an era of pandemic it is rarely seen in history, as the founding General Manager of a young institution that is only two years old, I would like to state that I am proud of the contributions that USHAŞ has made regarding Turkey's performance against the COVID-19 pandemic. In this guide that we have prepared jointly with UNDP, we have share our experiences on the production and distribution processes of protective materials. COVID-19 has taught us how important it is for each country to be able to produce protective materials and other necessary equipment in order to overcome the challenges of a global pandemic. I hope and wish that this guide, which we have prepared, contributes to countries in establishing their own protective material supply chains and in being much more prepared for the pandemics that humanity may face in the future.

Mehmet Ali Kılıçkaya
General Manager of USHAŞ
Deputy Chairman of the Board of USHAŞ




The COVID-19 pandemic has led to a dramatic loss of human life and a severe human development crisis where, in some dimensions, conditions are equivalent to levels of deprivation last seen in the 1980s¹. During this crisis as many as 70% of small and medium sized enterprises (SMEs) have had to shut down operations², causing an explosion in unemployment rates across the globe. Companies continue to struggle with the implementation of measures that ensures the health and safety of their employees such as protective equipment, which have become a scarce resource since the outbreak of the pandemic.

The private sector has a pivotal role in UNDP's integrated COVID-19 response with its critical know-how, reach, and resources. However, the private sector is also bearing the full impact of the crisis. UNDP's main objective is to keep all people, households, and businesses afloat during the COVID-19 crisis while collaborating with the private sector to safeguard its resilience and viability in order to preserve and advance the SDGs.

Considering the ramification on the economy, private sector engagement in economic cooperation provides significant impact through its agility, innovative spirit, and efficiency during the response to COVID-19. For instance, South-South investment flows which became an important financing source for the developing countries allow technological and knowledge spillovers while strengthening their productive capacity.

The private sector can contribute to the South-South cooperation with its investments, expertise, networks, and technological solutions which can improve the efficiency and effectiveness of governments' response to COVID-19. The Istanbul International Center for Private Sector in Development (IICPSD) supports companies in tailoring their business models to respond to development needs by identifying and promoting best practices within the framework of South-South Cooperation to achieve the SDGs³.

Under its thematic area, the IICPSD has the mandate to identify the best practices and success stories that the private sector and other stakeholders (governments, regulators, business associations) in emerging markets such as Turkey, Korea, Singapore, Indonesia, and others, have achieved in the last two decades and share experiences within the framework of the South-South Cooperation. This is to be done in collaboration with other UNDP Global Centers including the UNDP Seoul Policy Center, the UNDP Global Centre for Technology, Innovation and Sustainable Development, and TKA. One of the major issues that has evolved out of this pandemic is the large gap between supply and demand of

¹ COVID-19 and Human Development: Assessing the Crisis, Envisioning the Recovery | Human Development Reports (undp.org)

² OECD

³ UNDP Private Sector COVID 19 Service Offer, 2020 (https://www.undp.org/content/dam/angola/docs/Publications/UNDP_AO_%20Private%20Sector%20COVID-19_ServOffice.pdf)

EXECUTIVE SUMMARY

Personal Protective Equipment (PPE). WHO has called upon industries and governments to increase the manufacturing of PPE in order to meet the demand most importantly for healthcare workers to fight the pandemic, but indeed also the general population across the world.

In this context, UNDP IICPSD and Uluslararası Sağlık A.Ş. (USHAŞ), which is a healthcare enterprise owned by the Ministry of Treasury and Finance of the Republic of Turkey, affirmed their commitment to explore joint capacity building opportunities in the transfer of know-how and to facilitate the communication between Turkey and partner countries about high-quality PPE production, particularly within the framework of South-South Cooperation. This commitment was formalized through a Memorandum of Understanding signed by both parties.

Within this framework, this report has been developed by IICPSD and USHAŞ with the intention of providing the most vital information for potential future local PPE manufacturers as a one-stop-shop solution. Through this report, we hope to provide the readers comprehensive information, all related to manufacturing of PPE, on the following: input materials as well as resource requirements, the necessary equipment/components, the international standard requirements for production facilities and PPE based on the market to be served, capacity building/skills requirement for labor force, and financial assessment including the unit prices and total cost of the production.

Further to the technical assistance provided by IICPSD on PPE manufacturing presented in this report, with its extensive network of Public and Private partners; IICPSD is well positioned to identify, replicate, and scale up good practices to build a better future for next generations. We are aware the challenges of making our world a better place will never end and so does our effort to tackle with them.

Sahba Sobhani
Director of IICPSD



On 31 December 2019, the World Health Organization (WHO) was informed of cases of pneumonia of unknown cause in Wuhan City, China. A novel coronavirus was identified as the cause by Chinese authorities on the 7th of January 2020 and was temporarily named "2019-nCoV (C=VID19)".¹ On the 30th of January, The Director-General declared the novel coronavirus outbreak a public health emergency of international concern (PHEIC), WHO's highest level of alarm.² As the virus spread globally, WHO officially declared COVID-19 a pandemic on the 11th of March 2020 as per the definition "the worldwide spread of a new disease".³ With pharmaceutical companies and governments investing billions of dollars in the search for a vaccine to COVID-19, the first vaccine from Pfizer/BioNTech,⁴ Moderna,⁵ and AstraZeneca/Oxford University⁶ have already started to emerge. But before the vaccine can be produced and distributed at a scale to which herd immunity will be achieved is a significant challenge and may take up some time, therefore, contingency plans and the extensive measures taken such as the mandatory usage of masks and social distancing measures will continue to play an important role for many months and possible years. The pandemic has severely impacted all communities. As such self-sufficiency within the quarantined communities through a collaborative approach is required in the response.⁴

Based on the available evidence, "transmission of SARS-CoV-2 occurs primarily between people through direct, indirect, or close contact with infected people through infected secretions such as saliva and respiratory secretions, or through their respiratory droplets, which are expelled when an infected person coughs, sneezes, talks or sings".^{1,8} The people most at risk of infection are those who are in close contact with COVID-19 patients such as the healthcare professionals who care for COVID-19 patients. The most vulnerable are elderly and people with preexisting conditions such as diabetes, cancer, heart disease and others.⁹

Personal Protective Equipment (PPE) is an important measure in preventing transmission of COVID-19, not only in healthcare settings, diagnostic, and treatment centers but also in daily activities of individuals and general population. The US Food and Drug Administration (FDA) defines "Personal protective equipment (PPE) refers to protective clothing, helmets, gloves, face shields, goggles, facemasks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness."¹⁰ This guideline will be limited to the most commonly used PPE, gloves, surgical/isolation gowns, face shields, surgical/face masks, and respirators, with a primary focus on masks, most commonly used by the general population and healthcare workers. Furthermore, it is important to clarify the distinction between PPE intended for medical and non-medical use. Depending on the intended PPE to be produced, the standards may differ. The standards for PPE will be further elaborated in this report.

Demand for PPE has reached unprecedented levels as COVID-19 has spread globally and governments have sought to prepare and respond. National stockpiling strategies by affected countries have further driven up demand.¹¹ Supply availability has been hampered by several issues, including export restrictions by some countries producing PPE, and lockdowns that have forced suppliers to (temporarily) shut down. The PPE supply chain has not been properly functioning to meet a surge in demand due to the constraints in production, materials, and logistics. Prices of PPE products have risen dramatically since the beginning of the COVID-19 outbreak: a six-fold increase for surgical masks; threefold for respirators; and a doubling in the price of gowns. Hence, it is vital to understand the bottlenecks and risks to overcome backlogs in the production and distribution of PPE.¹²

The United Nations Framework for the immediate socio-economic response to COVID-19 includes shared responsibility, global solidarity and urgent action for people in need and calls for protecting jobs, businesses, and livelihoods to set in motion a safe recovery of societies and economies as soon as possible for a more sustainable, gender-equal, and carbon-neutral path—better than the "old normal".¹³

FREQUENTLY ASKED QUESTIONS⁴

The private sector has a pivotal role in UNDP's integrated COVID-19 response with its critical know-how, reach, and resources. UNDP's main objective is to keep all people, households, and businesses afloat during the COVID-19 crisis while collaborating with the private sector to safeguard its resilience and viability in order to preserve and advance the SDGs. While the private sector is suffering from a heavy impact of the crisis, the private sector can also play a significant role in the immediate response to COVID-19, helping governments to leverage their existing capacities such as in the production of the PPEs. Within this framework this report provides an outline to all stages of the PPE supply chain, including the procurement of raw materials, production lines, quality assurance, certification, and the supply of products to the individuals and health workers.

This guideline has been written with the intention of providing the most vital information for future PPE manufacturers as a one-stop-shop solution. Hence, the intended audience of this guideline is any potential PPE manufacturer, including private sector companies, public sectors and other institutions that may wish to produce PPE. The content of the report covers information on input materials as well as resource materials, the necessary equipment/components, the International standard requirements for production facilities and PPE, capacity building/skills requirement for the involved labor force, and financial assessment including the unit prices and total cost of the production. The report also showcases lessons learned, experience, good practices from Turkey including the measures taken to overcome the challenges of coordinating the production line, dealing with the bottlenecks in the PPE value chain, and distributing PPE domestically and internationally.

This guideline draws upon key sources including but not limited to WHO's most recent publications on COVID-19 and PPE standard requirements and technical specifications, IFC's tool for determining cost of production of PPE, OECD's PPE value chain analysis, WTO's overview on the export/import restrictions, the Asian Development Bank's PPE market analysis, the International Labor Organization's framework for occupational health and safety, the Food and Drug Administration and European Commission's technical and standard guidelines for PPE, and other important publications on PPE manufacturing and distribution.

1. How rapidly can a company convert a part of its manufacturing facility into a PPE mask and gown manufacturing facility?

Manufacturers using multiple cutters can switch very easily to PPE production, with some changes in consumables. For instance, garment and textiles manufacturers can easily convert their production lines to manufacture PPE, provided the required health regulatory guidelines (if needed), hygienic and other standards are met (read more on standards in Chapter 4).

For other manufacturers, conversion could be more difficult and require more time and investment in additional capacity and equipment. For manufacturers considering transforming entirely on their own would need a lot longer and are therefore advised to seek expert help for a smoother transition.

2. Can anyone produce Health Care Facility Grade PPE Products?

When considering an investment in PPE manufacturing, it is important to understand that it is not an easy, one-time investment. Choosing the right machinery and procuring the appropriate raw materials and labour are very important matters. Hence, it is important that a potential manufacturer of PPE clearly defines the quality assurance (QA) standards of the products to be produced upfront, as the raw materials as well as the testing protocols will determine whether a product will be certified for market access. This report seeks to answer these questions in further detail throughout the report with a focus of the PPE types face shields, gloves, coveralls, gowns, respirators and face masks, with a primary focus on masks, which are most commonly produced by new manufacturers.

How should raw materials be chosen?

There are four key raw materials for producing Health Care Facility Grade surgical masks or respirators: meltblown non-woven fabric, spunbond non-woven fabric, nose bridge wires, and earloops. Of these, the most important and costly is the meltblown non-woven fabric. The filtering efficiency of meltblown fabric cannot be determined simply by feel and appearance; it needs to be tested. It is therefore important to work with companies that are known for their quality and adherence to standards. The selection of materials also need to adapt to the local context and the materials available in the local and international markets. Beyond the selection of materials, the manufacturing process also needs to be carefully evaluated. For example, using heat sealed seams instead of sewn seams.

The barriers to non health care facility grade PPE products are less. For example, in most countries, face coverings used by the public, schools and businesses are not regulated, though there still exists an ethical responsibility to make products that do not cause harm to the public by putting them more at risk.

3. What alternative fabrics can be used for making gowns?

Wetlaid non-woven fabrics are an alternative for gown manufacturing, but they must meet the standards (See Chapter 4). There have been reports of wetlaid material that does not pass the viral barrier standards.¹⁴ Spunbond or Spunbond Meltblown Spunbond (SMS) non-wovens should also be procured cautiously as some lightweight materials do not protect either the wearer or the patient.

Due to the surge in demand for PPE, procurement practitioners and QA teams in different markets across the world have started to experience a rise in unethical practices, including fraudulent certificates and reports of sub-standard equipment being delivered. Due to these reasons, tougher due diligence mechanics have been put in place and it is therefore increasingly important to use certified raw materials and to obtain the necessary standard certification through the notified bodies depending on the market of export. For more information on standards and certification, please see chapter 3, 4, and 5.¹⁵

4. How can the best mask-making machines and suppliers be found?

Besides the procurement of raw materials, the correct choice of machinery plays a key role. Machinery is important not only for optimising production, but also for producing qualified masks. A machine manufacturer with export experience and a perfect remote after-sales service system should be chosen, so that the machine can be delivered to the customer safely and quickly, and the customer can quickly master the commissioning and use of the machine and begin production.

⁴This section draws on the following sources: Euratex: Face Mask Production, Requirements, Testing and Standards (<https://euratex.eu/covid-19/protective-garments/faq-face-masks-production-requirements-testing-and-standards/>); Baker & McKenzie: Manufacturing Personal Protective Equipment (<https://www.bakermckenzie.com/en/insight/publications/2020/03/manufacturing-personal-protective-equipment>); Textex Textiles: (a) The Production, Purchase and Use of Masks (<https://www.testtextile.com/the-common-faq-about-the-production-purchase-and-use-of-masks-complete-guide/>), (b) The Traps of Mask Production: The Most Critical and Latent (<https://www.testtextile.com/the-traps-of-mask-production-the-most-critical-and-latent/>); US Food and Drug Administration: Questions about Personal Protective Equipment (PPE) (<https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/questions-about-personal-protective-equipment-ppe>), and Centers for Disease Control and Prevention: Personal Protective Equipment: Questions and Answers (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>).

5. What are the cleanroom and sterilization requirements for PPE?

Typically, cleanroom standards are required for manufacturers whose customers include organisations in the healthcare industry. If the customers are hospitals or clinics which have patients who could be exposed to bacteria or viruses or are undergoing surgery, then the equipment will need to be sterilised. There are regulations and standards ensuring this. The company should pay attention to both international and local requirements, depending on the intended markets.

For example, manufacturers of masks are required to have at least ISO 8 clean room specifications. ISO 8 is the least clean room classification. A clean room must have less than 35,200,000 particles >0.5 micron per cubic meter and 20 HEPA filtered air changes per hour.¹⁶

1. How can companies/public sector/other institution ensure their products are safe/effective and get their products certified and are compliant with the standards and requirements in place today?

This depends on the local regulations in the country of manufacture and intended markets, as such the standard requirement and technical specification necessities will be defined not only by the origin of production but also the market in which the PPE will be used. Typically, there are fewer standards for civil use and non-medical standards.¹⁷ Nevertheless, in order to cater to large demand markets such as the US and the European Union, the standards, which will be further elaborated in chapter 4. For medical or healthcare use, there will be higher requirements for standards in place. The World Health Organization has provided a technical and standard specifications overview for different PPE¹⁸, which will be further elaborated in this report (see Chapter 4 for more details).

CHAPTER 1: Guidance on Material Resource Needs for PPE Manufacturing

This chapter is structured in the following way: First, a definition of PPE will be provided. Secondly, the different types of PPE that can be produced based on these guidelines will be described. Lastly, the key materials and resources used to produce PPE, as well as how they are manufactured will be defined, in order to understand the necessary inputs for production of PPE. The reason for using non-woven fabric, which is the most essential materials for masks, respirators and gown PPE manufacturing (not including face shields, goggles, and gloves), will be described as well as a detailed description of how to produce it for PPE manufacturing.

Definition of PPEs

Personal Protective Equipment (PPE) refers to equipment that protects its user against health or safety risks at work and public use. The International Labour Organization defines "PPE is equipment that will protect the user against the risk of accidents or of adverse effects on health."¹⁹ Likewise, the definition of PPE by the European Commission is "PPE are products that the user can wear or hold, to be protected against risks either at work, at home or whilst engaging in leisure activities."²⁰ Lastly, the US Food and Drug Administration (FDA), describes PPE the following way "PPE refers to protective clothing, helmets, gloves, face shields, goggles, facemasks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness."²¹ PPE is commonly used in health care settings such as hospitals, doctor's offices, and clinical labs, but due to COVID-19 PPE is used in public spaces by individuals. When used properly, PPE acts as a barrier between infectious materials such as viral and bacterial contaminants and your skin, mouth, nose, or eyes (mucous membranes).

PPEs Covered in the Report

As the focus of this guideline is the supply of protective equipment related to the COVID-19 pandemic, PPE for individuals and professionals as protection from COVID-19 is the primary focus. As such, surgical and respiratory masks, coveralls, face shields and gowns will be described in this part of the chapter.

Surgical masks / face masks

Depending on their quality, surgical masks or face masks have a range of intended uses from purely private use to use by health professionals during healthcare procedures. These masks are loose-fitting, disposable devices that create a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment.²²



Respiratory mask (N95, FFP2, FFP3, KN95)

A respiratory mask is a protective device designed to achieve the highest level of safety for the wearer through a very close facial fit and efficient filtration of airborne particles. The edges of the respirator are designed to form a seal around the nose and mouth. There are two main categories:

- The Air-Purifying Respirator, or Particulate Respirator, in which respirable air is obtained by filtering a contaminated atmosphere. These devices protect their wearers by filtering particles out of the air as they breathe. These respirators provide protection only against particles-not gases or vapour. N95, FFP2, FFP3 and KN95 masks are in this category.
- The Air-Supplied Respirator, in which an alternate supply of air is delivered for breathing.

Within each category, different techniques are employed to reduce or eliminate noxious airborne contaminants²³.



Face shields

Face shields are simple PPE that consist of a visor, a lightweight plastic or metal frame, and a suspension system that attaches the shield to the wearer's head. Face shields are often used as a secondary extra layer of protection over other protective equipment such as masks and/or goggles. The protective lens plate can be made up of plastics such as polycarbonate, propionate, acetate, polyvinyl chloride, and polyethylene terephthalate glycol (also known as PETG). For the comfort of the user, the plastic is often given anti-glare, anti-fog, anti-static, or other coatings. The attached suspension systems can include elastic straps, Velcro, headbands, glasses-type temple bars, pin-lock, or ratchet systems.²⁴



Coveralls and disposable coveralls

Coveralls are one-piece products designed to cover the whole body and other clothing to protect against dirt or other outside contaminants. They are often used by healthcare professionals. Coveralls are loose fitting for ease of movement, with sleeves, full leggings and often a hood to cover the head. They can also include over-shoe elements to cover footwear and protect against contamination²⁵.



Isolation and surgical gowns

Isolation and surgical gowns are examples of personal protective equipment used in health care settings. Both isolation and surgical gowns are used to protect the wearer from exposure to blood, body fluids, and other infectious materials, or to protect patients from infection. Additionally, the surgical gowns can block the colonization/adhesion of the medical staff's skin or clothing. Various bacteria on the surface are transmitted to surgical patients, effectively avoiding cross-infection of multi-drug resistant bacteria such as methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant enterococci (VRE). Therefore, the barrier function of surgical gowns is the key to reducing the risk of infection during surgery²⁶.



Medical gloves

Medical gloves are items of personal protective equipment that are used to protect the wearer and/or the patient from the spread of infection or illness during medical procedures and examinations. Medical gloves form one part of an infection-control strategy. They can be made of various polymers including latex, nitrile rubber, polyvinyl chloride, and neoprene. They come either unpowdered or powdered with corn starch for lubrication²⁷.



Materials used for PPE Manufacturing

The single most important material used to produce PPE such as masks is the non-woven fabric, which is an engineered fabric with different functions, the primary reason for it to be used for masks and other PPE is the ability to filter out particles that may contain the virus. Below, non-woven fabric will be explained as well as the reasons to use it for PPE. Then the resources used to produce it will be defined and lastly the production of non-woven will be outlined.

Non-woven fabric as a material for PPE manufacturing

This report will mostly focus on the non-woven fabric materials as they are the most common in use. Non-woven fabrics are engineered fabrics that may be either single-use (disposable) or highly durable. They are used in numerous applications, including baby diapers, wet wipes, surgical drapes and covers, liquid cartridge and bag filters, face masks, air-conditioning filters, soil stabilizers and roadway underlayment, drainage systems, and disposable clothing.

Non-woven fabrics are superior to linens in the reduction of air-borne contamination and are regarded as the most effective materials for bacterial barriers. They have undergone significant development and can be designed to meet medical needs, performing much better than their woven counterparts in terms of cost, effectiveness, disposability, and similar criteria. In hospitals, cross-contamination is always a major challenge and is largely attributed to the re-use of woven gowns, masks and other similar articles which can become contaminated and potentially spread germs. The advent of non-wovens has facilitated the development of a more cost-effective alternative which are disposable and has reduced the problem of cross-contamination greatly²⁸.

Why non-wovens for medical products?

Non-woven fabrics are the optimal products for performance in specialised tasks such as environments where medical-level safety is required. This is because they are flexible in the way they can be designed. According to the website www.technicaltextile.net, the properties which make non-woven fabrics the best choice for medical products are²⁹:

- Excellent barrier properties
- Superior efficiency
- Better performance (comfort, thickness and weight, water vapour transmission, air permeability etc.)
- Increased protection for user due to better physical properties like tensile properties, tear resistance, abrasion resistance etc.)
- Less potential for cross contamination

Wound care was and still is the primary use for medical and surgical non-wovens.



Materials used in medical non-wovens

The fibres used in medical non-wovens can be classified into two categories: natural and synthetic. The natural fibres used are wood-pulp, cotton, and rayon. Wood pulp is used due to its obvious absorbency, bulk, and low cost. However, the production of wood pulp, primarily coming from the bleaching process has a high environmental impact. Furthermore, the pulp manufacturing need a large volume of process water, producing large amounts of wastewater³⁰. Hence, it is important to be congrisant of managing the process under which the purchased wood pulp has been produced, to reduce the environmental impact.

According to the same source³¹, the reasons why natural fibres make excellent medical non-wovens are as follows:

- They are highly absorbent of exudate and blood.
- They offer excellent breathability.
- They have good aesthetic characteristics.
- They are easily laundered and can be sterilized.
- They have excellent dimensional stability and can operate at high temperatures (~175°C).
- They are biodegradable.
- They drape and conform well.
- They are resistant to heat.
- They have excellent water retaining capacities.
- They are non-allergenic and non-irritant.

Synthetic medical non-wovens are based on polypropylene, which is valued for its excellent rheological characteristics, and for its hydrophobicity, which is desired in some systems where barrier properties are required. These materials provide these advantages at a reasonably low cost. Bicomponent fibres are widely used in thermal bonding and add functionality. Polyester, for example, is used when strength, mechanical properties and ease of sterilization are of prime importance. Synthetic fibres also add to the strength, solvent resistance, and static dissipation of the products in which they are used.

These synthetic fibres have the following advantages in the production of PPE³²:

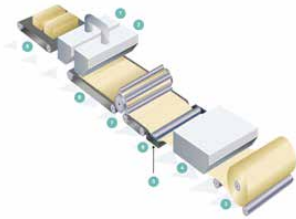
- They are easy to process.
- They are cost effective.
- They offer a better performance due to their strength and low density.
- They are non-hazardous and easy to dispose of.

The non-woven manufacture process

The process of manufacturing non-woven fabrics involves the following stages: forming the fibrous web; entangling or bonding the fibres in the web to impart mechanical integrity to the structure of the product; and finishing the fabric to obtain the special properties required for the PPE to be produced³³. These steps are further described below:

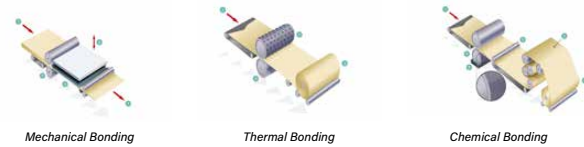
Formation of the web

The qualities of the final product – the mask or any other item of PPE – are determined by the fibrous web formed in the early stages of manufacturing the material. Initially, the formation of webs from staple-length fibres was carried out through a "textile carding" process, whereas the formation of webs from short fibres was based on a wet laid process similar to papermaking. These two techniques are still in use today, but more recently a method has been developed to form a web directly from filaments immediately after they exit an extruder. This process is called spun laying²⁴.



Bonding the web

There are various techniques for bonding the fibres in the web.



Needle punching is a process of bonding non-woven web structures by mechanically interlocking the fibres throughout the web. Fibres are punched into the web by means of barbed needles, which are mounted on a board. These are then withdrawn, leaving the fibres entangled.

Stitch bonding is a method of consolidating fibre webs using knitting elements with or without yarn to interlock the fibres. Different types of yarn can be used. Common examples of the use of the resulting materials are vacuum bags, geo-textiles, filtration materials and interlinings. In many applications stitch-bonded fabrics are taking the place of woven goods because they are faster to produce and the cost of production is therefore considerably lower.

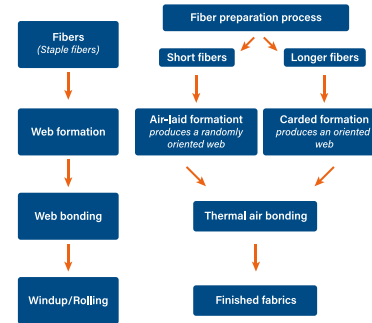
Thermal bonding refers to the use of heat to bond or stabilise a web structure, which results in a thermoplastic fibre. All parts of the fibres act as thermal binders, thus eliminating the use of latex or resin binders. Thermal bonding is the method most commonly used in the manufacture of goods such as baby diapers. Polypropylene is the most suitable fibre as it has a low melting point of approximately 165°C. The fibre web is passed between heated calendar rollers for bonding. The use of smooth rolls bonds the entire surface of the fabric, increasing the strengt, but reducing the drape and softness.

Chemical bonding is one of the most common methods of bonding. A chemical binder is applied to the web, which is then cured. The most commonly used binder is latex, because it is most cost efficient, easy to apply and very effective. The methods used to apply the binder include saturation bonding, spray bonding, print bonding and foam bonding.

Hydro entanglement, finally, is the process of using fluid forces to lock the fibres together. This is achieved by directing fine water jets through the web, which is supported by a conveyor belt. Entanglement occurs when the water strikes the web and the fibres are deflected. The vigorous agitation within the web causes the fibres to become entangled.

Finishing and Converting

Finishing and converting are the last operations performed on the fabric before it is delivered to the customer. Finishing includes operations aimed at imparting particular surface properties, such as coating and laminating, calendering and embossing, corona and plasma treatments designed to alter the wettability of the fabric, and wet chemical treatments to impart anti-static, anti-microbial and/or flame-retardant properties. After the fabric has been finished, it is cut into the desired size for the final product – a process known as converting²⁵.



Useful links for non-woven manufacturing

The following links provide useful information about non-woven manufacturing:

Non-wovens Industry Magazine: [Nonwovens Industry](https://www.nonwovens-industry.com/) (https://www.nonwovens-industry.com/)

Technical Textile: [Nonwoven Manufacturing](https://www.technicaltextile.net/articles/nonwoven-manufacturing-7188) (https://www.technicaltextile.net/articles/nonwoven-manufacturing-7188)

Textile Technology: [Nonwovens Manufacturing Process](https://textechdip.wordpress.com/contents/nonwoven-2/#:~:text=Figure%203-,WEB%20FORMATION,mechanical%2C%20chemical%20%2Cand%20thermal%20.) (https://textechdip.wordpress.com/contents/nonwoven-2/#:~:text=Figure%203-,WEB%20FORMATION,mechanical%2C%20chemical%20%2Cand%20thermal%20.)

Edana: [How are Nonwovens Made?](https://www.edana.org/nw-related-industry/how-are-nonwovens-made) (https://www.edana.org/nw-related-industry/how-are-nonwovens-made)

Textile Today: [Types of non-woven fabric, manufacturing processes and applications](https://www.textiletoday.com.bd/types-non-woven-fabrics-manufacturing-processes-applications/) (https://www.textiletoday.com.bd/types-non-woven-fabrics-manufacturing-processes-applications/)

Thomasnet.com: [How to Make Personal Protective Equipment \(PPE\) for COVID-19 \(Manufacturing and Sourcing Guide\)](https://www.thomasnet.com/articles/plant-facility-equipment/how-to-make-ppe/#register) (https://www.thomasnet.com/articles/plant-facility-equipment/how-to-make-ppe/#register)

IFC: [Production of Personal Protective Equipment \(PPE\)](https://www.ifc.org/wps/wcm/connect/cdb117e4-6de2-4946-9a1f-79db16766bbf/Steps+in+starting+PPE+manufacturing.pdf?MOD=AJPERES&CVID=n7LVVCw) (https://www.ifc.org/wps/wcm/connect/cdb117e4-6de2-4946-9a1f-79db16766bbf/Steps+in+starting+PPE+manufacturing.pdf?MOD=AJPERES&CVID=n7LVVCw)

CHAPTER 2: Guidance on Facilities and Equipment Needed for PPE Manufacturing

The previous chapter outlined the materials and resources used for the PPE used for individuals and healthcare professionals as protection for COVID-19. This chapter will be divided into two main topics, the first will outline the hygienical standard requirements for facilities in which PPE is produced. The second part will revolve around the production of PPE and what machinery and other equipment are needed depending on the desired output.

Hygiene standards

The single most important common requirement for all PPE production facilities is the cleanliness of the facility, equipment, and material. The spaces to be used for storing materials and for manufacturing, packaging, and storing products should be constructed so as not to allow any type of contamination. Cleanrooms are used for manufacturing where high levels of cleanliness and sterility are required. In order to achieve this objective, the facility should have proper air circulation and ventilation to prevent access of microorganisms or other similar sources of contamination. It should also be designed in a way that does not allow dust to spread in the manufacturing area.

PPE manufacturing facilities operate under strict hygienic standards. The number of dust particles equal to or greater than 0.5 microns may not exceed 3.5 million per cubic metre. In addition, the maximum number of planktonic bacteria allowed is 500 per cubic metre³⁸.

Furthermore, natural rubber allergies, also referred to as latex allergy, is an important aspect to be cognisant of when producing PPE. The molecular sizes of allergen proteins fall within the range of 5,000-80,000 Daltons, with the protein of molecular size of 14,600 thought to be the major allergen. The number of reported incidents has risen dramatically with some studies suggesting that up to 17% of individuals in employment, which brings them into contact with latex products, (laboratory workers, dental and health professionals) may be at risk³⁹. Most commonly, latex is used in a variety of PPE including gloves and masks.

The difference in pressure between adjacent cleanrooms must be ≥ 5 Pa, and the difference in pressure between a cleanroom and any other room is ≥ 10 Pa. This is mainly to ensure that air flows from clean areas towards non-clean areas and not vice versa, so as to avoid the possibility of unhygienic air. The recommended temperature of the cleanroom is 20-22°C in winter and 24-26°C in summer, with a fluctuation of $\pm 2^\circ\text{C}$. The recommended humidity is between 30% and 50% in winter and between 50% and 70% in summer³⁸.

The principles of cleanroom design for medical devices must support three objectives:

1. Suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.
2. Adequate space for orderly placement of equipment and materials to prevent mix-ups and contamination, and
3. Adequate flow of materials and persons to prevent contamination.

Cleanroom classifications³⁹

Air Changes by Cleanroom Classification						
Cleanroom Standard	Cleanroom Classification Guidelines					
ISO 14644-1	Class 3	Class 4	Class 5	Class 6	Class 7	Class 8
Federal Standard 209E	1	10	100	1	10	100
EU GMP	-	-	A/B	-	C	D
Air changes /hour	360-540	300-540	240-480	150-240	60-90	5-48
For cleanrooms and clean zones						

This table details the recommended air changes per hour for ISO 14644-1:2015 cleanrooms and their associated GMP Grade and Federal Standard

ISO 14644-1:2015 Cleanroom Classification						
This table details the air clean/liness class by particle concentration						
ISO Classification Number	Maximum allowable concentrations (particles/m ³) for particles equal to and greater than the considered sizes, shown below					
	$\geq 0.1 \mu\text{m}$	$\geq 0.2 \mu\text{m}$	$\geq 0.3 \mu\text{m}$	$\geq 0.5 \mu\text{m}$	$\geq 1 \mu\text{m}$	$\geq 5.0 \mu\text{m}$
ISO Class 1	10 ^b	d	d	d	d	e
ISO Class 2	100	24 ^b	10 ^b	d	d	e
ISO Class 3	1	237	102	35 ^b	d	e
ISO Class 4	10	2,37	1,02	352	83 ^b	e
ISO Class 5	100	23,7	10,2	3,52	832	d,e,f
ISO Class 6	1,000,000	237	102	35,2	8,32	293
ISO Class 7	c	c	c	352	83,2	2,93
ISO Class 8	c	c	c	3,520,000	832	29,3
ISO Class 9 ^e	c	c	c	35,200,000	8,320,000	293

For cleanrooms and clean zones shown in ISO 14644-1:2015

Cleanroom Limits for Airborne Particulate Contamination					
Clean room and clean air device classification, in relation to GMP (2008).					
Cleanroom Standard	Maximum permitted number of particles /m ³				
EU GMP Grade	ISO 14644-1	At rest $\geq 0.5 \mu\text{m}$	At rest $\geq 5.0 \mu\text{m}$	In operation $\geq 0.5 \mu\text{m}$	In operation $\geq 5.0 \mu\text{m}$
A	5	3,52	20	3,52	20
B	5	3,52	29	352	2,9
C	7	352	2,9	3,520,000	29
D	8	3,520,000	29	Not defined	Not defined

For cleanrooms and clean zones

Additional sources of information about cleanroom classifications

Production Automation Corporation: [Class 2 - 3 Medical Device Cleanrooms](https://blog.gotopac.com/2018/12/20/cleanroom-design-medical-device-class/#:~:text=and%20Temperature%20Calibration-,Cleanroom%20Design%20for%20Injection%20Molded%20Medical%20Devices,ISO%20Class%207%2D8%20cleanroom)
(<https://blog.gotopac.com/2018/12/20/cleanroom-design-medical-device-class/#:~:text=and%20Temperature%20Calibration-,Cleanroom%20Design%20for%20Injection%20Molded%20Medical%20Devices,ISO%20Class%207%2D8%20cleanroom>)

Connect2Cleanrooms: [Cleanroom Classifications](https://www.connect2cleanrooms.com/knowledge-base/cleanroom-classifications)
(<https://www.connect2cleanrooms.com/knowledge-base/cleanroom-classifications>)

Temizoda.org.tr: [Standards for Classification of Cleanrooms](https://www.temizoda.org.tr/media/files/ClassificationOfCleanrooms2005.pdf)
(<https://www.temizoda.org.tr/media/files/ClassificationOfCleanrooms2005.pdf>)

American Cleanroom Systems: [FAQs about Clean Room Classifications](https://www.americancleanrooms.com/cleanroom-classifications/#:~:text=A%20cleanroom%20must%20have%20less%20than%2035%2C%20200%2C000%20particles%20%3E0.5,100%2C000%20particles%20per%20cubic%20foot.)

(<https://www.americancleanrooms.com/cleanroom-classifications/#:~:text=A%20cleanroom%20must%20have%20less%20than%2035%2C%20200%2C000%20particles%20%3E0.5,100%2C000%20particles%20per%20cubic%20foot.>)

Manufacturing of PPE

The machinery needed to manufacture PPE, and the level of sophistication, depend on the expected output. Although full automation is theoretically possible, in the primary proportion of PPE manufacturing lines, manual labour is still required as most available machines are unable to complete all aspects of mask production. This makes manufacturing of PPE a labour intensive exercise, which offers opportunities for SMEs in lower-cost markets to have a competitive advantage. The manufacturing processes for each category of PPE product will be explained below.

Mask Manufacturing

The requirements for facilities manufacturing medical or particle filtering masks are similar. Automated machines manufacture the mask bodies in multiple layers. These machines collate the different layers, cut them out and perform the ultrasonic sewing of the mask body. Some are also able to place the nose clip inside at the same time.

Many of the machines available on the market cannot fix the ear loops or head harness at the same time as they produce the mask body. The ultrasonic sewing of the ear loops or head harness is therefore done by manual labour using additional machines. Since this process is not fully automated, it is slower than mask body manufacturing. Manufacturers should estimate the number of additional machines that will be needed with the comparative speeds of the two production processes in mind (i.e., five ear loop fixing machines for every mask body manufacturing machine).

There are three types of mask-making machine⁴⁰.

Model	Semi-automatic mask-making machine	Automatic mask-making machine	Fully automatic mask-making machine
Output	Theoretical: 90~110pcs/min Actual: 80~90pcs/min	Theoretical: 90~110pcs/min Actual: 80~90pcs/min	Theoretical: 120pcs/min Actual: 80~90pcs/min
Debugging	Little debug difficulty, stable operation	Little debug difficulty, stable operation	Debug difficult, Harder to stabilize operation
Remarks	Requires dozens of people to weld the earloops, produces about 150,000 in 24 hours	Requires two people to operate, produces about 100,000 in 24 hours	Requires one person to operate, produces about 100,000 in 24 hours

The theoretical output of masks defines the scenario where the line of the production will not have to stop due to lack of input such as that of non-woven, earlaps, and others, break due to technical issues, and other issues that may occur in the manufacturing process. As such, the actual is a conservative estimation of output.

Medical face mask production

1. The basic structure and functions of disposable medical masks



2. Technical specifications and standards for medical masks

Common testing standards for masks are as follows (Standards will be elaborated in Chapter 3).

- EN 149 "Respiratory protective devices - Filtering half masks to protect against particles - Requirements testing marking"
- EN 14683 "Medical face masks - Requirements and test methods"
- ASTM F2100 "Standard Specification for Performance of Materials Used in Medical Face Masks"
- CFR 42 Part 84 "NIOSH Guide to the Selection and Use of Particulate Respirators"
- EN 14168 "Medical face masks. Requirements and test methods"
- GB 2626 "Respiratory protective equipment. Non-powered air-purifying particle respirator"

3. The formal production process of medical masks

The raw non-woven materials are hung on the mask sheeter rack, and the machine produces the masks automatically after calibration in a fully automatic production line. After the first phase, the mask sheet emerges and is transferred to the ear band machine for ultrasonic welding, which is an industrial process whereby high-frequency ultrasonic acoustic vibrations are locally applied to workpieces being held together under pressure to create a solid-state weld. Lastly, the mask is sterilized with ethylene oxide and left for seven days to volatilise. The specific process is as follows:

1. Combine three layers of non-woven fabric.
2. Stitch the metal wire fixed by the nose clip into the laminated three-layer non-woven fabric.
3. Fold mask to make pleats.
4. Cut to a single mask unit.
5. Fix the ear loop to the four corners of the mask using the ultrasonic welding device.
6. Disinfect.

During the whole process of mask production, it is important to ensure that the mask bodies maintain a stable shape and size. This also ensures the stability of the earloop welding⁴¹.

4. Equipment required for medical masks



TM120 Semi-automatic Medical Mask Making Machine



TM100 Automatic Medical Mask Production Line

The equipment normally needed for a mask manufacturing line producing disposable medical masks includes mask forming machines, mask crimping machines, mask trimming machines, nose bridge line fitting machines, and earband spot welding machines. A semi-automatic medical mask production line can work up to 130,000 pieces per day under full-time operation and can be upgraded to an automatic line.

5. How to control the product quality and safety of disposable masks

Since the quality of filter materials for medical masks is difficult to check by convenient and effective means of inspection, enterprises must mainly ensure the quality of their products by standardising the operation of the production quality management system so that they can be audited through registration technology reviews and system assessments. Inspectors will pay attention to the production process and the source of supply of the filter materials. To ensure the quality of their products, enterprises should check the filtering materials used in their products, clarify the sources and quality requirements, and have relatively stable production processes and sources of supply.

6. Medical mask quality inspection

Primary medical masks can be sold in the market only after specific items have been tested and approved, since they are to be used for medical purposes. The testing of disposable medical masks includes both factory inspection and type inspection (For information on standards, see Chapter 5)⁴².

Fully automatic mask making

1. Advantages of a fully automatic mask-making machine

The mask slicers required for semi-automatic and fully automatic production lines are identical. The difference between the two processes comes at the earloop welding stage. While semi-automatic production requires manual welding (stitching), and hence debugging is very simple, fully automatic production involves automatic welding after slicing, but machine debugging becomes more complicated, although faulty products are identified more easily. Fully automatic production is therefore a more optimal process when compared to semi-automatic production provided that the mask-making machine has been set up correctly by the manufacturer. In addition to stability and high speed, a fully automatic mask making machine saves at least ten employees compared to a semi-automatic mask making machine⁴³.

2. Types of fully automatic mask-making machine

The automatic mask-making machines on the market are generally divided into automatic "one-tractor" mask-making machines and "one-tractor two" mask-making machines. Experience in the production of mask-making machines and market research suggest that a "one-tractor" mask machine is more practical and more efficient than a "one-tractor two" machine. With the latter machines, it is difficult to match the film-making machine with the two welding machines and the middle parting system, and there are four conveyor belts. If any part fails, the whole line will have to stop, so the machine can usually only be operated very slowly, producing no more than 60 pieces/minute.

A "one-tractor" mask-making machine consists only of a mask slicer and a welding machine, with a single conveyor belt, reducing the probability of a total line stoppage. In addition, because there are fewer components to fit together, the "one-tractor" fully automatic mask making machine can produce at high speed⁴⁴.

3. Speed vs. stability

Theoretically, the machine will run consistently at normal speeds, but once the speed exceeds a certain threshold, the machine is prone to run out of order and quality cannot be guaranteed. Manufacturers must therefore identify the speed range that can guarantee both volume output and the required quality requirements in order to meet the standards for markets. Typically, the speed and stability of the machine is ideal when the speed is in the range of 80pcs/min~100pcs/min⁴⁵.

4. Commissioning and durability

The manufacturer needs to know how soon the operator will be able to start operating the machine skilfully, how soon the machine will be able to produce a stable batch, and how frequently it will run out of order. These issues affect the production schedule, the company's tolerance for error and the risk of losses. When buying a machine, it is important to ask how long the manufacturer has been debugging it, what problems have been solved, and how often the machine will run out of order under normal circumstances⁴⁶.

Additional information on medical face mask production

Euratex: [FAQ on Face Mask Production, Requirements, Testing and Standards](https://euratex.eu/covid-19/protective-garments/faq-face-masks-production-requirements-testing-and-standards/) (https://euratex.eu/covid-19/protective-garments/faq-face-masks-production-requirements-testing-and-standards/)

Testex Textiles: [The Complete Guide for the Medical Masks Production](https://www.testextextile.com/fighting-the-coronavirus-top-6-knowledge-to-know-before-investing-in-establishing-disposable-medical-mask-production-lines/) (https://www.testextextile.com/fighting-the-coronavirus-top-6-knowledge-to-know-before-investing-in-establishing-disposable-medical-mask-production-lines/)

Testex Textiles: [What does the Mask Making Machine Look Like?](https://www.testextextile.com/what-does-the-best-seller-mask-making-machine-look-like/) (https://www.testextextile.com/what-does-the-best-seller-mask-making-machine-look-like/)

Testex Instrument Ltd.: [Video Link: Medical Face Mask Making Machine](https://www.youtube.com/watch?v=a9m5qM54vCk) (https://www.youtube.com/watch?v=a9m5qM54vCk)

Testex Textiles: [Global Standards for Face Masks](https://www.testextextile.com/global-standards-for-face-masks-fullest-version-update/) (https://www.testextextile.com/global-standards-for-face-masks-fullest-version-update/)

Testex Textiles: [Mask Production Traps](https://www.testextextile.com/the-traps-of-mask-production-the-most-critical-and-latent/) (https://www.testextextile.com/the-traps-of-mask-production-the-most-critical-and-latent/)

Respirator (N95, FFP2, FFP3, KN95) manufacturing

There are two basic types of respirators: air filtering and air-supplying. Air filtering respirators (such as an N95 respirator or mask) stop contaminants, bacteria, and other matter from reaching the wearer's nose and mouth. Air supplying respirators supply the user with clean air from a tank or other uncontaminated source (for example, a Self-Contained Breathing Apparatus)⁴⁸.

Structure and materials of N95 masks

A medical N95 respirator consists of multiple layers of non-woven fabric, often made from polypropylene as described in Chapter 1. The two outward protective layers of fabric, covering the inside and outside of the mask, are made of spunbond materials. Spun bonding uses nozzles blowing melted threads of a thermoplastic polymer (often polypropylene) between 15 and 35 micrometers in length onto a conveyor belt. The layers of threads build up into cloth as the belt continues down the line. The fibres are then bonded using thermal, mechanical, or chemical techniques. The two outer layers of the respirator, between 20 and 50 g/m² in density, act as protection against the outside environment as well as a barrier to anything in the wearer's exhalations⁴⁹.

Between the spunbond layers is a pre-filtration layer, which can be as dense as 250 g/m², and the filtration layer. The prefiltration layer is usually made of a needled non-woven fabric. This type of non-woven material is needle-punched to increase its cohesiveness. This is accomplished by sending barbed needles repeatedly through the fabric to hook the fibres together. The prefiltration layer is then run through a hot calendaring process, in which the plastic fibres are thermally bonded by running them through heated high-pressure rollers. This makes the pre-filtration layer thicker and stiffer, so that it can be moulded into the desired shape and will hold that shape as the mask is used.

The filtration layer is made of a high efficiency meltblown electret (or polarised) non-woven material. It is this which determines the efficiency of the filtration. Meltblowing is a process similar to spun bonding, in which multiple machine nozzles use air to spray threads of melted synthetic polymers onto a conveyor. However, the fibres are much smaller: less than a micron wide. As the conveyor continues, the threads build up, bonding naturally as they cool to create the fabric. Meltblown fabric is sometimes thermally bonded as well, to add strength and abrasion resistance, although the fabric then begins to lose some of its key characteristics.

Respirator-Making Machinery (N95, KN95, FFP2, FFP3)

The respirators are made by machinery which combines the layers through ultrasonic welding (stitching) and adds straps and metal strips to adjust the mask over the user's nose. The respirators are then sterilized⁴⁹.

Three different types of machines are required in the manufacturing process⁴⁹:

1. Automatic Mask Body Forming Machine (1 set): This is used to produce the mask bodies automatically. It includes an ultrasonic welding device to weld together the 4- 5 layers of mask fabric materials from the feeding system. It produces mask bodies in die-cut shape with nose clip bars inserted.
2. Earloop Ultrasonic Welding Machine (4 sets recommended). These are used to weld the earloops onto the the mask bodies produced in the previous process. They feature an earloop feeding system. The mask body is positioned and the machine automatically completes the welding at four points.
3. Mask Edge Ultrasonic Welding Machine (3 sets). These are used to weld the four edges together to produce folded masks. They feature six workstations on a rotating surface: one mask is completed at each rotation.

Additional information on respirator production

Testex Textiles: [Respirator Mask Making Machine](https://www.testextile.com/product/KN95-mask-machine/) (https://www.testextile.com/product/KN95-mask-machine/)

Kuayuda: [Fully Automatic N95 Mask Making Machine](https://www.youtube.com/watch?v=4EMRxU8rhwg) (https://www.youtube.com/watch?v=4EMRxU8rhwg)

Suny Group: [Semi Automatic N95 Mask Making Machine](https://www.youtube.com/watch?v=gS48_EjLp-c) (https://www.youtube.com/watch?v=gS48_EjLp-c)

Coveralls manufacturing and machinery

Another important PPE is the coveralls, which are primarily used for professional healthcare workers in hospitals or other potentially highly contaminated areas of work.

PPE body coveralls are made in two steps. First, a coverall is stitched using normal machines such as a single-needle lockstitch machine or a three-thread overall machine. An overlock machine is a better choice for all seams, except for those attaching the front zipper, since it produces an even seam margin at higher speed. Secondly, all the seams are sealed by a hot air seam sealing machine using seam sealing tape.

The bulk cutting of the coveralls patterns is done in the same way as in industrial garment production, and the same straight knife cutting machine can be used. The finished coveralls are sterilized using a sterilization machine. They are then folded manually, and each item is placed inside a polybag⁵¹.

For additional information, see:

Online Clothing Study: [PPE Coverall Manufacturing Resources](https://www.onlineclothingstudy.com/2020/06/ppe-overall-manufacturing-resources.html) (https://www.onlineclothingstudy.com/2020/06/ppe-overall-manufacturing-resources.html)

H&H Asia Group: [PPE Coverall Production](https://www.youtube.com/watch?v=EzPT1iIKpiY&feature=youtu.be) (https://www.youtube.com/watch?v=EzPT1iIKpiY&feature=youtu.be)

Gown manufacturing and machinery

Gowns are examples of personal protective equipment used in health care settings. They are used to protect the wearers from the spread of infection or illness if they come into contact with potentially infectious liquid and solid material. They may also be used to help prevent the gown wearer from transferring microorganisms which could harm vulnerable patients, such as those with weakened immune systems.

The design of medical/isolation gowns does not provide continuous whole-body protection since there are possible openings in the back and they only cover the body down to the mid-calf⁵².

The machines used in the production of gowns are the same as for overalls – namely, single-needle lockstitch machines, three-thread overlock machines, hot air seam sealing machines and straight knife cutting machines. There are also fully automatic gown machines on the market.

For additional information, see:

US Food and Drug Administration: [Medical Gowns](https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns#---text=A%20surgical%20gown%20is%20a%20body%20fluids%2C%20and%20particulate%20matter.&text=Surgical%20gowns%20can%20be%20used,(Levels%201%2D4) (https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns#---text=A%20surgical%20gown%20is%20a%20body%20fluids%2C%20and%20particulate%20matter.&text=Surgical%20gowns%20can%20be%20used,(Levels%201%2D4)

Thomasnet: [How to Make Protective Gowns for COVID-19](https://www.thomasnet.com/articles/other/how-to-make-protective-gowns-for-coronavirus-covid-19/) (https://www.thomasnet.com/articles/other/how-to-make-protective-gowns-for-coronavirus-covid-19/)

Google Patents; [Method of Manufacturing Surgical Gown](https://patents.google.com/patent/US20130318693) (https://patents.google.com/patent/US20130318693)

CHAPTER 3: Guidance on Quality Assurance - Management System Requirements and Production Quality Control Systems for PPE and Medical Device Manufacturing

In this chapter, first the importance of an established and well functioning Quality Assurance and Conformity Assessment Process for successful manufacturing of PPE, will be emphasized. Secondly, the key International Organization for Standardization (ISO) standards important for the manufacturing of PPE will be listed and described in detail. Lastly, a detailed list of the standards connected to specific PPE from WHO will be listed.

Quality assurance and conformity assessment of PPE

The challenges posed by the COVID-19 pandemic have increased the importance of quality assurance and conformity assessment processes. The secret to successfully manufacturing a product, such as an item of PPE, which is fit for its intended purpose lies in addressing quality issues right from the beginning. In order to ensure the quality and suitability of the product, the manufacturer needs to establish a robust manufacturing system capable of manufacturing the product continuously and consistently achieving the expected quality.

The manufacturing quality control system should encompass the whole of the manufacturing process from the input of the raw or semi-finished materials to the manufacturing itself and the packaging of the finished product. All the processes that form part of this manufacturing lifecycle need to be empowered, managed, and monitored in such a way as to achieve a robust manufacturing process and ensure the quality of the product.

Environmental, Social, Governance (ESG) due diligence for quality assurance

Sustainability is playing an increasingly important role for consumers around the world, in fact "Half of global respondents (49%) say they're inclined to pay higher-than-average prices for products with high-quality/safety standards, which consumers often associate with strong sustainability practices"⁵³ Hence, sustainable business practices play an increasingly important role to maintain trust with clients, consumers, employees, shareholders, and local communities, which will strengthen the brand of the manufacturer and ensure a more smooth path to market accession. Furthermore, adhering to sustainable business practices allows for manufacturers to stay ahead of the regulatory curve and helps to retain talent. Indeed, 46% of survey respondents said that they "would only work for companies with sustainable business practices."⁵⁴

Human Rights due diligence

Human Rights and labour standards are two of the most important pillars of the Social aspect of ESG. During the pandemic, an increasing amount of PPE with a lack of supply chain transparency found its way to the market, which further amplified the need for stringent regulatory measures to ensure that the products meet the standards of ensuring no labour exploitation is taking place and that Human Rights are upheld.⁵⁵ The United Kingdom introduced the UK Modern Slavery Act in 2015⁵⁶, Australia followed suit in 2018 with the Australian Modern Slavery Act⁵⁷, and as of next year, the European Union has announced the introduction of the Human Rights Due Diligence legislation to be tabled in 2021⁵⁸. In other words it is becoming ever more important to maintain a robust oversight quality assurance mechanisms within the supply chain from purchasing of raw materials to production and distribution, in order to ensure international market access.

UNDP's initiative Business and Human Rights in Asia has created a simple and accessible tool, "Human Rights Due Diligence and COVID-19: Rapid Self-Assessment for Business" (Rapid self-assessment tool), to help manufacturers consider and manage the human rights impacts of their operations⁵⁹. The tool is not to be considered a fully-fledged human rights impact assessment, but will help producers identify potential points of improvement within their value chain.

Additional links to ESG and Human Rights due diligence

Danish Institute of Human Rights: [Toolkit on Human Rights for Procurement Policy Makers and Practitioners \(March 2020\)](#)

Verite [Guiding Principles for Responsible Businesses](#) for the COVID-19 Pandemic and a guidance note on COVID-19 and Vulnerability to Human Trafficking for Forced Labor

The [WalkFree, Global Slavery Index](#), highlights the prevalence estimates of people living in modern slavery country-by-country in 2018

The [CSR Risk Check](#) is a CSR risk assessment tool

International standards for quality assurance

There are a number of international standards for management systems which manufacturers may adopt with a view to ensuring the quality of their manufacturing processes and products. The most widely used and accepted international standards are listed below.

[The importance of ISO certification cannot be underestimated as it shows that your company can be trusted.](#)

Standard Codes	Content
ISO 9001:2015	Quality Management Systems – Requirements
ISO 14001:2015	Environmental Management Systems – Requirements with Guidance for Use
ISO 45001:2018	Occupational Health and Safety Management Systems – Requirements with Guidance for Use
ISO 26000:2010	Guidance on Social Responsibility
ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
GMP	Good Manufacturing Practices

ISO 9001: 2015 – Quality Management Systems

The ISO 9001: 2015 standard "specifies requirements for a quality management system when an organization:

- Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.⁶⁰

The ISO 9001 requirements are set out by ISO in ten clauses. All the requirements of ISO 9001:2015 are generic and are intended to be applicable to any organization, regardless of its type or size or the products and services it provides. Mandatory requirements need to be complied with, while non-mandatory requirements may be submitted for documentation purposes.

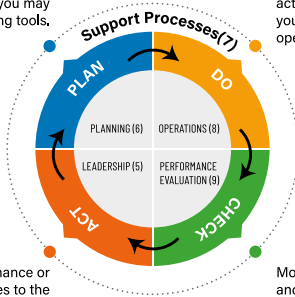
Some of the main benefits of ISO 9001 certification include:

- Suitability for both small and large organizations
- Better internal management
- Less overhead
- Increase in efficiency, productivity, and profit
- Improved customer retention and acquisition
- Consistent outcomes, measured and monitored
- Globally recognised standard
- Compatibility with other ISO standards

The process approach in ISO 9001:2015

In accordance with the requirements of ISO 9001 the following sequence of actions provides examples of how an organization may choose to build and control the processes of its quality management system. Performance can be managed and improved by applying the Plan-Do-Check- Act (PDCA) cycle as seen below.⁶¹ This applies equally to the system as a whole, to individual processes and to operational activities. PDCA operates as a cycle of continual improvement, with risk-based thinking at each stage. For further information, see **The Process Approach in ISO 9001:2015** (<https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/iso9001-2015-process-appr.pdf>).

Setting the objectives for the improvement activities and addressing risks. Here you may use quality planning tools.



Realizing the improvement using the planned activities. These activities will be incorporated in your quality activities for the operation of the QMS.

Optimizing the performance or introducing changes to the improvement with practice of leadership and commitment.

Monitoring, measuring, analyzing and evaluating the performance and effectiveness of the improvement using tools for performance evaluation.

ISO 14001:2015 Environmental Management Systems

ISO 14001 is an international standard in designing and implementing environmental management systems (EMS) that organizations can be certified for voluntarily.⁶² ISO 14001 certification enhances green credentials, which subsequently boosts business image. At the same time, it improves cost control and reduces accidents or incidents caused by environmental factors.

ISO 14001 is not merely a certificate of adherence to environmental management standards, but also a long-term commitment to keep improving environmental performance. This will be increasingly important for longer-term business viability, as public procurement entities, including public medical procurement entities, will continue to strengthen the sustainability requirements for public procurement activities. As such, ISO 14001 can be a minimum requirements for market access and bid consideration

The ISO 14001:2015 requirements are broadly separated into 10 sections or clauses. For further information on ISO 14001:2015, see the ISO 14001: 2015 Implementation Guide (<https://www.bsigroup.com/globalassets/localfiles/en-th/iso-14001/iso-140012015/iso-14001-implementation-guide.pdf>).

ISO 45001: 2018 Occupational Health and Safety Management Systems

ISO 45001:2018 specifies the requirements for an occupational health and safety management system, and gives guidance for its use, to enable organizations to provide safe and healthy workplaces by preventing work-related injury and ill health, as well as by proactively improving their health and safety performance⁶³.

ISO 45001:2018 is applicable to any organization that wishes to establish, implement and maintain a management system to improve occupational health and safety, eliminate hazards and minimize occupational health and safety risks (including system deficiencies), take advantage of occupational health and safety opportunities, and address occupational health and safety management system nonconformities associated with its activities.

ISO 45001:2018 helps an organization to achieve the intended outcomes of its occupational health and safety management system. Consistent with the organization's occupational health and safety policy, the intended outcomes of an occupational health and safety management system include:

- continual improvement of performance
- fulfilment of legal and other requirements
- achievement of objectives.

For further information on ISO 45001:2018, see:

BSI Group: **ISO 45001:2018 International Standard for OH&S** (https://www.bsigroup.com/globalassets/localfiles/en-nz/45001/bsi0044---1803_nz_iso-45001-migration-guide-web.pdf)

ISO26000: 2010 Guidance on Social Responsibility

ISO 26000:2010 provides guidance to all types of organizations, regardless of their size or location, on⁶⁴:

- concepts, terms, and definitions related to social responsibility
- the background, trends, and characteristics of social responsibility
- principles and practices relating to social responsibility
- the core subjects and issues of social responsibility
- integrating, implementing, and promoting socially responsible behaviour throughout the organization and, through its policies and practices, within its sphere of influence
- identifying and engaging with stakeholders
- communicating commitments, performance and other information related to social responsibility.

ISO 26000:2010 is intended to assist organizations in contributing to sustainable development. It is intended to encourage them to go beyond legal compliance, recognizing that compliance with law is a fundamental duty of any organization and an essential part of their social responsibility. It is intended to promote common understanding in the field of social responsibility, and to complement other instruments and initiatives for social responsibility, not to replace them⁶⁵.

The Seven Key Principles, advocated as the roots of socially responsible behaviour, are:

- Accountability
- Transparency
- Ethical behaviour
- Respect for stakeholder interests (Stakeholders are individuals or groups who are affected by, or have the ability to impact, the organization's actions)
- Respect for the rule of law
- Respect for international norms of behaviour
- Respect for human rights.

The Seven Core Subjects, which every user of ISO 26000 should consider, are:

- Organizational governance
- Human rights
- Labor practices
- Environment
- Fair operating practices
- Consumer issues
- Community involvement and development.

For further information on ISO 26000, see:

International Organization for Standardization: [ISO 26000 and OECD Guidelines](https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100418.pdf) (https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100418.pdf)

International Organization for Standardization: [ISO 26000:2010 Guidance on social responsibility](https://www.iso.org/standard/42546.html#:~:text=ISO%2026000%3A2010%20is%20intended,part%20of%20their%20social%20responsibility.) (https://www.iso.org/standard/42546.html#:~:text=ISO%2026000%3A2010%20is%20intended,part%20of%20their%20social%20responsibility).

ISO13485: 2016 Medical Devices – Quality Management Systems

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support)⁶⁸. The requirements in this International Standard can also be used by suppliers or other external parties providing product (e.g. raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services) to such organizations. The supplier or external party can voluntarily choose to conform to the requirements of this International Standard or can be required by contract to conform.

When used within a quality management system, such an approach emphasizes the importance of:

- a) understanding and meeting requirements.
- b) considering processes in terms of added value.
- c) obtaining results of process performance and effectiveness.
- d) improving processes based on objective measurement.

For further information on ISO 13485:2016, see:

International Organization for Standardization: [ISO 13485:2016 Medical devices Quality management systems and Requirements for regulatory purposes](https://www.iso.org/obp/ui#iso:std:iso:13485:ed-3:v1:en) (https://www.iso.org/obp/ui#iso:std:iso:13485:ed-3:v1:en).

Good Manufacturing Practices

Good Manufacturing Practices (GMP) is a system of processes, procedures, and documentation that help ensure that products are consistently produced and controlled according to quality standards. These practices are required to conform to guidelines and regulations recommended by agencies that control authorization and licensing for the manufacture and sale of food, drug products, and active pharmaceutical products including products such as PPE⁶⁷.

GMP guidelines and regulations address many issues that can influence the safety and quality of a product. Some of these are:

- Hygiene – facilities must maintain a clean and hygienic manufacturing area
- Controlled environmental conditions, to prevent contamination and cross contamination
- Clear definition and control of manufacturing processes
- Clear and unambiguous instructions and procedures
- Training of operators to carry out and document procedures
- Maintaining records during manufacture, either manually or by means of instruments to demonstrate compliance with these guidelines and regulations
- The retention in a comprehensible and accessible form of records of the manufacturing process (including distribution) that enable the complete history of a batch to be traced
- The minimization of any risk to the quality of products during their distribution
- The availability of a system for recalling any batch of the product from sale or supply
- The examination and investigation of complaints, and the adoption of appropriate measures for the defective products and for preventing recurrence.

Organizations that meet GMP or cGMP (current Good Manufacturing Practices) requirements will not only comply with the legislation, but also will commit themselves to a programme which will substantially increase the quality of their product and increase revenues and customer satisfaction⁶⁸.

Some other benefits of implementing GMP are that they:

- outline a quality system that reduces or prevents errors
- ensure products are safe
- prevent and control contamination and cross-contamination
- prevent mislabeling and adulteration
- provide a better understanding and comply with the relevant laws and regulations
- enhance international credibility and public image.

For further information on GMP, see:

International Organization for Standardization: [Good Manufacturing Practices \(GMP\) for Quality Standards](https://isoupdate.com/standards/gmp/) (https://isoupdate.com/standards/gmp/)

Child labour

The elimination of child labour in all sectors is an international goal and each country is obliged to make it a national goal.

According to ILO, "child labour" is "work that deprives children of their childhood, their potential and their dignity, and that is harmful to physical and mental development." It refers to work that⁶⁹:

- is mentally, physically, socially, or morally dangerous and harmful to children, and/or
- interferes with their schooling by: depriving them of the opportunity to attend school; obliging them to leave school prematurely, or requiring them to attempt to combine school attendance with excessively long and heavy work.

The worst forms of child labour involves children being enslaved, separated from their families, exposed to serious hazards and illnesses and/or left to fend for themselves on the streets of large cities – often at a very early age. Whether or not particular forms of "work" can be called "child labour" depends on the child's age, the type and hours of work performed, the conditions under which it is performed and the objectives pursued by individual countries. The answer varies from country to country, as well as among sectors within countries⁷⁰.

Applicable standards for PPE and medical device product performance

For procurement purposes, this section will define the minimum requirements for PPE in a given market for healthcare and general population usage. The most commonly used standards are the EU standards and US standards. In the following chapter, the standard requirements for manufacturing purposes will be thoroughly defined for all markets.

As PPE plays an essential role in the health and safety of both workers and in healthcare and for private use, the legislation makes it obligatory for products to meet some minimum functionality or performance criteria in every country and/or region that the PPE will be used. These minimum performance levels are then generally specified in the national, regional, or international product standards in effect in the market in question.

Based on these national, regional, or international standards, manufacturers are expected to prove the performance of their products. The tables below, developed by WHO^{71,72} and the European Accreditation (EA)⁷³, indicate the standards that apply to PPE products used during the pandemic in different countries/regions.

WHO list of standards for different types of PPE

(This information is based on the WHO report on technical specifications for PPE as of 13th of November 2020)

PPE Products

Item	Characteristics	Performance standards
Gloves, medical examination (non-sterile)	Gloves, examination, nitrile (preferable), latex, polychloroprene or PVC, powder-free, non-sterile (e.g. minimum 230 mm total length). Minimum thickness 0.05 mm. Sizes S, M, L.	EN 455, EN 374, optional additional: ASTM D6319, D3578, D5250, D6977 Or alternative equivalent set of standards
Gloves, surgical (sterile)	Gloves, surgical, nitrile (preferable), latex, polyisoprene or polychloroprene, sterile, powder-free, single use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Minimum thickness 0.10 mm. Sizes ranging 5.0–9.0.	EN 455 ASTM D3577 Sterility: United States Pharmacopeia EN ISO 11607 Or alternative equivalent set of standards
Face shield	Made of clear plastic and providing good visibility to both the wearer and the patient. Adjustable band to attach firmly around the head and fit snugly against the forehead. Fog-resistant (preferable). Completely covers the sides and length of the face, may be re-usable (made of robust material which can be cleaned and disinfected) or disposable.	<ul style="list-style-type: none"> EN 166 (if reusable), ANSI/ISEA Z87.1 (if reusable), or alternative equivalent set of standards
Particulate respirator	Good particle filtration (minimum 94% or 95%), good breathability with design that does not collapse against the mouth (e.g. duckbill, cup-shaped). May be tested for fluid resistance. (NIOSH/FDA surgical N95, EN 149 FFP2+Type IIR, GB 19083 Grade/Level 1)	Fluid resistant respirator: <ul style="list-style-type: none"> Minimum NIOSH approved (42 CFR Part 84) and FDA cleared "surgical N95" EN 149, minimum "FFP2" and EN 14683 Type IIR GB 19083, minimum "Grade/Level 1", or alternative equivalent standard Non-fluid resistant respirator Minimum NIOSH approved "N95" according to 42 CFR Part 84 EN 149, minimum "FFP2" GB 2626, minimum "KN95" or alternative equivalent standard

Item	Characteristics	Performance standards
Mask, medical -for healthcare worker	Medical mask, good breathability, Internal and external faces should be clearly identified, 98% droplet filtration, preferably fluid resistance.	Fluid resistant masks (surgical masks): <ul style="list-style-type: none"> EN 14683 Type IIR ASTM F2100 Level 1, 2 or 3, YY 0469, with at least 98% bacterial droplet filtration or alternative equivalent standard Non-fluid resistant mask: <ul style="list-style-type: none"> EN 14683 Type II YY/T 0969, with at least 98% bacterial droplet filtration or alternative equivalent standard
Mask, medical, for patient	Medical mask, good breathability, Internal and external faces should be clearly identified.	<ul style="list-style-type: none"> EN 14683 Type I YY 0469 or YY/T 0969, if bacterial droplet filtration is below 98% or alternative equivalent standard
Scrubs, tops	Tunic/tops, woven, scrubs, reusable or single use, short sleeved (tunic/tops), worn underneath the coveralls or gown.	
Scrubs, pants	Trouser/pants, woven, scrubs, reusable or single use, worn underneath the coveralls or gown.	
Apron, heavy duty	Straight apron with bib, Fabric: 100% polyester with PVC coating, or 100% PVC, or 100% rubber, or 100% reusable and biodegradable material, or other fluid resistant coated material, Waterproof, sewn strap for neck and back fastening or single-material cut film, Minimum basis weight: 300 g/m ² , Thickness: 200-300 microns, optional, Covering size: 70 - 90 cm (width) x 120 - 150 cm (height), Reusable (provided appropriate arrangements for decontamination are in place) or biodegradable.	<ul style="list-style-type: none"> EN ISO 13688 EN 14126 and partial protection (EN 13034 or EN 14605) EN 343 for water and breathability or alternative equivalent set of standards If biodegradable, <ul style="list-style-type: none"> EN 13432, ASTM D6400
Apron, disposable	Single-use straight sleeveless protective apron, for use in healthcare settings. Seamless liquid proof and stain resistant, Comfortable to wear, apron has back- and neck-band strips attached (4 in total), Both back- and neck-band can be adjusted/ fastened, Colour: white, Material: polyethylene (PE) or biodegradable or compostable material, Size: 85 x 145 cm (w x l) (+/- 15%), Thickness: not less than 50 um, Able to resist water and disinfectant (ethanol 70% and chlorine solution 0.05% or 500ppm).	Product performance testing if biodegradable <ul style="list-style-type: none"> EN 13432, ASTM D6400 or alternative equivalent set of standards

Item	Characteristics	Performance standards
Gown, isolation	Single use, disposable, of non-woven material, Length: mid-calf, Sizes S, M, L, XL May also be reusable, Critical zones may be more fluid-resistant than non-critical zones, Reusable gowns should meet the minimum performance requirements after maximum suggested laundering cycles.	<ul style="list-style-type: none"> AAMI PB70 (Level 1-3) and ASTM F3352, EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cm H2O AAMI PB70 Level 4 and ASTM F3352 or ISO 16604 Class 5 or alternative equivalent set of standards
	Single use, disposable, of non-woven material, Length: mid-calf, Sterile or non-sterile. Critical zones may be more fluid resistant than non-critical zones. Or Single use, woven material, length mid-calf, sterilizable. Critical zones may be more fluid resistant than non-critical zones. Reusable gowns should meet the minimum performance requirements after maximum suggested laundering cycles.	<ul style="list-style-type: none"> AAMI PB70 and ASTM F2407 EN 13795 EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cm H2O YY/T 0506 or alternative equivalent set of standards EN 556, if sterile or alternative equivalent set of standards
	Glove should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Minimum 280 mm total length. Sizes: S, M, L. Reusable. Heavy duty gloves. High cracking, puncture- and abrasion-resistant. Powder free, seamless, and entirely waterproof. Made of nitrile, synthetic rubber (no latex). Knit inner lining facilitates slide-in and removal. Cleanable with water and disinfectant (resisting both ethanol solutions 70% and chlorine solutions 0.05% or 500 ppm). Material thickness, at level of the fingers, not less than: 0.38 mm. Length not less than: 30 cm. Supply co-packed as one left/right pair.	<ul style="list-style-type: none"> EN 388 ANSI 105 EN 374-1, EN 374-2 (at least Level 2) EN 374-4 and EN 374-5 EN 420 + A1 Or alternative equivalent set of standards

Respirators

Item	Europe (EN 149)	USA (NIOSH CFR PART 84)	China (GB 2626)	China (GB 19083)
Filtration (NaCl)	≥ 94% (FFP2)	≥ 95% (N95)	≥ 95% (KN95)	≥ 95% (Grade 1)
Breathing resistance (inhalation)	≤ 70 Pa (@ 30 L/min) ≤ 240 Pa (@ 95 L/min) ≤ 500 Pa (clogging)	≤ 343 Pa (@ 85L/min)	≤ 350 Pa (@ 85L/min)	≤ 343 Pa (@ 85L/min)
Breathing resistance (exhalation)	≤ 300 Pa (@160 L/min)	≤ 245 Pa (@ 85L/min)	≤ 250 Pa (@85 L/min)	
Fit	Tested with 10 human participants	Fit testing upon arrival	10 participants	Fit factor of 100, with 8 subjects
Total inward leakage	≤ 8% leakage (arithmetic mean)	n/a	≤ 8% leakage (arithmetic mean)	
CO2 of inhalation air	≤ 1%	n/a	≤ 1%	
Synthetic Blood penetration	If Type IIR 120 mm Hg (≥29/32 passing masks)	If surgical N95, 120 mm Hg (≥29/32 passing masks)	none	If surgical N95, 120 mm Hg (5 masks)
Other criteria	Requires passing paraffin oil filtration at 95%			

Medical Masks

Item	Europe (EN 14683)	US (ASTM F2100)	China (YY 0469)	China (YY 0969)
Filtration (BFE)	≥95% (Type I) ≥98% (Type II, IIR)	≥95% (Level 1) ≥98% (Level 2, 3)	≥95% (ASTM F2101)	≥95% (ASTM F2101)
Filtration (PFE)	N/A	≥95% (Level 1) ≥98% (Level 2, 3)	N/A	N/A
Pressure drop (Pa/cm²)	<40 (Type I, II) <60 (Type IIR)	mm H2O/cm2 <49 Pa or 5 mm H2O/cm2 (Level I) <58.8 Pa or 6 mm H2O (Level II, III)	<49	<49
Synthetic blood penetration (kPa)	120 mm Hg ISO 22609 ≥16 kPa (Type IIR)	80 mm Hg (Level I) 120 mm Hg or 16 kPa (Level II) 160 mm Hg (Level III)	120 mm Hg =16kPa	N/A
Microbial cleanliness (cfu/g)	≤30	N/A	≤100	≤100

Gowns, isolation/surgical

Item	Europe (EN 13795)	US (AAMI PB70, ASTM F3352, ASTM F2407)	China (YY T/0506)
Water resistance (impact penetration)		<4.5 g (AAMI Level 1) ≤ 1.0 g (AAMI Level 2 and 3) (AQL 4%, RQL=20%)	
Water resistance (hydrostatic pressure)	≥ 20 cm H2O (critical area, std performance) ≥ 100 cm H2O (critical area, high performance) ≥ 10 cm H2O (less critical area, std and high performance)	≥ 20 cm (AAMI Level 2) ≥ 50 cm (AAMI Level 3) (AQL 4%, RQL=20%)	≥ 20 cm H2O (critical area, std performance) ≥ 100 cm H2O (critical area, high performance) ≥ 10 cm H2O (less critical area, std and high performance)
Viral penetration		Pass (AQL 4%, RQL=20% (AAMI Level 4)	
Resistance to wet bacterial penetration	≤ 2.8 I ₀ (critical areas, std performance) ≤ 6.0 I ₀ (critical areas, high performance)		≤ 2.8 I ₀ (critical areas, std performance) ≤ 6.0 I ₀ (critical areas, high performance)
Resistance to dry microbial penetration	≤ 300 CFU (less critical areas, std and high performance)		≤ 300 CFU (less critical areas, std and high performance)
Cleanliness, microbial	≤ 300 CFU (all areas, std and high performance)		≤ 300 CFU (all areas, std and high performance)
Bursting strength (Dry)	≥ 40 kPa (all areas, std and high performance)		≥ 40 kPa (all areas, std and high performance)
Bursting strength (Wet)	≥ 40 kPa (critical areas, std and high performance)		≥ 40 kPa (critical areas, std and high performance)
Tensile strength (Dry)	≥ 20 N (all areas, std and high performance)	≥ 30 N	≥ 20 N (all areas, std and high performance)
Tensile strength (Wet)	≥ 20 N (crit. areas, std and high performance)		≥ 20 N (crit. areas, std and high performance)
Other criteria to consider		Optional: - Water vapour transmission Rate (ASTM D6701) - Evaporative resistance (ASTM F1868, Part B)	China (GB 38462) gown standard, in effect October 2020

Gloves, medical examination (non-sterile)

	Europe (EN 455)	US (ASTM material specific)
	EN 455-1, EN 455-2, EN 455-3, EN 455-4	D6319, D3578, D5250, D6977
Freedom from holes	AQL < 1.5 (ISO 2859)	AQL < 2.5 (ISO 2859)
Force at break (N) / Tensile strength (MPa) (after ageing)	AQL - N/A Nitrile >6.0N Latex (natural) >6.0N Polyisoprene >6.0N Polychloroprene > 6.0N PVC, PE > 3.6N	AQL < 4.0 (ISO 2859) Nitrile >14MPa Latex (natural) >14MPa Polychloroprene >14MPa PVC >11MPa
Powder residue content	<2.0mg	<2.0mg
Aqueous soluble protein content	<10 µg per g of glove	<200 µg/dm ²
Extractable antigenic protein content		<10 µg/dm ²

Gloves, surgical (sterile)

	Europe (EN 455)	US (ASTM material specific)
	EN 455-1, EN 455-2, EN 455-3, EN 455-4	D3577
Freedom from holes	AQL < 1.5 (ISO 2859)	AQL < 1.5 (ISO 2859)
Force at break (N) / Tensile strength (MPa) (after ageing)	AQL - N/A All materials > 9.0N	AQL < 4.0 (ISO 2859) Type 1- Latex (natural) >18MPa Type 2- Polyisoprene, Polychloroprene, Nitrile >12MPa
Powder residue content	<2.0mg	<2.0mg
Aqueous soluble protein content	<10 µg per g of glove	<200 µg/dm ²
Extractable antigenic protein content		<10 µg/dm ²
Sterility	ASTM refers o U.S. Pharmacopeia: pass/fail EN 455 refers to EN ISO 11607	

Common PPE standards for the EU market

Below is a summary of the standards and certification procedures applying to PPE products and medical devices widely used during the pandemic in the EU market¹⁶.

Items	Europe (EN 455)	US (ASTM material specific)
Isolation Gowns (Non Sterile)	93/42/EEC EN 13795	Declaration of Conformity by Manufacturer and CE Marking A third-party, independent evaluation may increase the reliability of the declaration of the manufacturer.
Isolation Gowns (Sterile)	93/42/EEC EN 13795	Certification by a Notified Body (NB), Declaration of Conformity by Manufacturer and CE Marking with NB number
Isolation Gowns as PPE	EU 2016/425 EN 13688 EN 14605 EN 13034 EN 14126:2004	Certification by a Notified Body (NB), Declaration of Conformity by Manufacturer and CE Marking with NB number
Coveralls (PPE)	EU 2016/425 EN 13688 EN 14605 EN 13034 EN 13982-1 EN 14126:2004	Certification by a Notified Body (NB), Declaration of Conformity by Manufacturer and CE Marking with NB number

Additional information

Additional information can be found at the following links:

European Commission: [EU legislation and PPE](https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment_en) (https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment_en)

European Commission: [List of Harmonized Standards for PPE in EU](https://ec.europa.eu/growth/content/first-lists-references-harmonised-standards-personal-protective-equipment-and-cableway_en) (https://ec.europa.eu/growth/content/first-lists-references-harmonised-standards-personal-protective-equipment-and-cableway_en)

ASTM International: [ASTM Standards](https://www.astm.org/COVID-19/) (https://www.astm.org/COVID-19/)

CEN-CENELEC (European Committee for Electrotechnical Standardization): [Chinese Standards for PPE](ftp://ftp.cenelec.eu/EN/COVID19/ENGTranslationsOfChineseStandards_Q41.zip) (ftp://ftp.cenelec.eu/EN/COVID19/ENGTranslationsOfChineseStandards_Q41.zip)

WHO: [Technical specifications for personal protective equipment \(WHO Recommendations\)](https://www.who.int/teams/health-product-and-policy-standards/access-to-assistive-technology-medical-devices/priority-medical-devices-for-covid/ppe-covid) (https://www.who.int/teams/health-product-and-policy-standards/access-to-assistive-technology-medical-devices/priority-medical-devices-for-covid/ppe-covid)

Testex Textiles: [Full Analysis of 9 Standards for Face Mask](https://www.testextextile.com/antiviral-face-mask-for-filtering-2019-ncov-full-analysis-of-nine-standards/) (https://www.testextextile.com/antiviral-face-mask-for-filtering-2019-ncov-full-analysis-of-nine-standards/)

UNICEF: [UNICEF Technical Requirements for PPE](https://www.unicef.org/supply/media/3851/file/technical-requirements-personal-protective-equipment-PPE.pdf) (https://www.unicef.org/supply/media/3851/file/technical-requirements-personal-protective-equipment-PPE.pdf)

CHAPTER 4: International Minimum Requirements for export of PPE and Medical Devices in selected markets/ territories

In this chapter, the specific standards and notified bodies/authorization institutions will be described in detail for manufacturing purposes. As a manufacturer it is important to be aware of the standard requirements from the export market that is targeted. Information about PPE standards for the European Union, US, Chinese, and Russian markets is given below, reflecting the importance of these markets for manufacturers across the globe of PPE.

European Union market

Under the terms of the Customs Union agreement with the European Union (EU), the Turkish market complies with regulatory measures of the EU since this is necessary to ensure the free movement of goods. In this context, Turkey's product quality and standardization infrastructure is also required to be in harmony with that of the EU in order to remove technical barriers to trade. The Ministry of Trade and the Turkey Quality Association have been working on strengthening the institutional and infrastructural framework for quality in Turkey. Manufacturers who want to export their products to the EU need to have all the quality certificates required by the EU Commission and CE marks.

As European countries are the primary export market for Turkish manufacturers, they mostly follow EU standards and regulations. They may also need to comply with the standards and regulations of other countries in order to export goods to the countries in question.

Regulations and directives

Minimum requirements for PPE across the EU are governed by regulations and directives, particularly the regulation EU 2016/425 on Personal Protective Equipment. For medical devices, the directive 93/42/EEC (Medical Device Directive, MDD) is still in force but will soon be replaced by the regulation EU 2017/745 (Medical Device Regulation, MDR)¹⁶.

The Essential Health and Safety Requirements which are given in Annex II of the regulation EU 2016/425 constitute the minimum requirements for PPE on the EU market. The regulation also includes a mechanism to identify whether or not a product is to be treated as PPE. When a product is considered to be an item of PPE, it is placed in to one of three categories depending on the risks which it is used to provide protection against. Once again, the details are set out in an annex to the regulation.

The CE mark on the product serves to assure end users that the PPE fulfils the corresponding Essential Health and Safety Requirements of the EU regulation on PPE.

Conformity assessment

The conformity assessment requirements for PPE products vary with the category of PPE to which they belong:

For Category 1, the conformity assessment can be conducted by the manufacturer. The manufacturer must conform to all the responsibilities stated in the regulation before affixing the CE mark on the product.

For Category 2, the conformity assessment must be conducted by a 'Notified Body' as a type examination only. The manufacturer must conform to all the responsibilities stated in the regulation before affixing the CE mark on the product.

For Category 3, the conformity assessment has to be conducted by a Notified Body as a type examination and the manufacturer must conform to all the responsibilities stated in the regulation before affixing the CE mark on the product. In addition, the Notified Body monitors the performance of the quality assurance system of the manufacturer and the CE mark may only be fixed on the PPE products with the identification number of the monitoring Notified Body¹⁶.

Notified Bodies for the EU market

Notified Bodies are the competent product evaluation and certification bodies authorized by EU member states for the evaluation of products in the EU market for their content and performance, in order to ensure that the products fulfil the Essential Health and Safety requirements for their intended use. The technical competence of Notified Bodies is assured by an accreditation system involving globally recognised accreditation. Further assessments are made by the authorities in the EU member state in question. When evaluating PPE products, Notified Bodies apply international standards (EN ISO/IEC 17065) and the EU regulations for PPE or medical devices. The authorization of Notified Bodies is the responsibility of EU member states and the European Commission⁷⁷.

A list of all authorized Notified Bodies is published on the European Commission web site, together with their locations and contact information and the fields of competence or product groups for which they have been authorized. This database tool is known as the NANDO (New Approach Notified and Designated Organizations) information system. The Bodies are listed under specific legislation and product groups. They can be filtered to see which of them are authorized for PPE and medical devices. Manufacturers can filter the Notified Bodies based on country, legislation, product group or the protection properties of the item of PPE with which they are concerned⁷⁸.

Additional links

More information relevant to the EU market can be found at the following links:

European Commission: [Producing new protective equipment for the EU market](https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment_en) (https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment_en)

European Commission: [Notified Bodies \(NANDO\) for the EU Market](https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment_en) (https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment_en)

European Commission: [Conformity assessment procedures for protective equipment](https://ec.europa.eu/docsroom/documents/42311) (https://ec.europa.eu/docsroom/documents/42311)

European Commission: [CE Marking for Manufacturers](https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en) (https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en)

European Law: [REGULATION \(EU\) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on PPE](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425)

European Commission: [FAQs on EXPORT REQUIREMENTS FOR CERTAIN PPE to the EU market](https://trade.ec.europa.eu/doclib/docs/2020/april/tradoc_158693.pdf) (https://trade.ec.europa.eu/doclib/docs/2020/april/tradoc_158693.pdf)

US market

Imports of PPE products entering the US are regulated by US Customs and Border Protection (Customs). Like other products, the import of PPE generally requires⁷⁹:

- the submission of entry documents
- payment of the estimated duties, including any additional tariffs (determined by the Office of the US Trade Representative (USTR) on the goods
- examination by, and release of the goods from, Customs

Depending on whether they are considered "medical devices," PPE products may also be subject to additional US Food and Drug Administration (FDA) entry documentation and registration requirements. In the light of the COVID-19 pandemic and supply shortages, Customs, the FDA, and the USTR have exercised their authority in an effort to reduce import burdens and make it easier for needed PPE products to enter the US⁸⁰.

First, Customs will "assist... in expediting the release of COVID-19 relief materials" but has advised importers that as much information as possible regarding the shipment and cargo should be provided, including:

- shipment information
- conveyance information
- cargo description
- country information
- the identity of the parties involved.

Customs has also provided a hub of COVID-19-resources, including a list of COVID-19 relief materials and their Harmonized Tariff Schedule of the United States (HTSUS) code numbers, which will help importers determine the duties and additional tariffs (described below) that apply⁸¹.

Second, the FDA has recently clarified its import requirements for three categories of PPE⁸²:

- non-FDA regulated products
- regulated products subject to an Emergency Use Authorization (EUA)
- regulated products subject to an FDA Enforcement Guidance.

FDA regulation

Typically, PPE products that are considered medical devices require FDA approval in order to be imported into and distributed throughout the US, as well as registration and pre-market notification with the agency⁸³.

The FDA has clarified that, for PPE products not considered medical devices ("intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease⁸⁴"), entry information should be transmitted to Customs; additional FDA entry filings and import requirements do not apply.

The FDA has advised that PPE is a regulated device "when [it is] intended for a medical purpose, such as prevention of infectious disease transmission (including uses related to COVID-19)." The PPE described in the guidance documents (including gowns, gloves, face masks and respirators) do not need to be intended for use in a hospital or other health facility to be considered a medical device.⁸⁵

On this basis, most of the PPE needed for use with COVID-19 will be regulated as a medical device because it is clearly intended for "a medical purpose" (i.e., the prevention of transmission of a highly infectious disease). Thus, as a practical matter, such PPE is subject to FDA regulation, but it currently benefits from the relaxed approval and clearance restrictions described below⁸⁶.

EUA-approved PPE

Entry information for imported PPE medical devices that are authorized for emergency use pursuant to an Emergency Use Authorization (EUA) should be submitted to the FDA and must comply with any specific requirements set out in the applicable EUA. An EUA allows unapproved medical devices (or unapproved uses of devices) to be imported and used in an emergency to treat or prevent severe illness.

PPE that are currently subject to an EUA include certain:

- diagnostic tests
- masks/respirators
- ventilators.

When filing entry documents and information for PPE with applicable EUAs, importers should specify an Intended Use Code of 940.000 (Compassionate Use/Emergency Use Device) and an appropriate FDA product code. For entries filed under this Intended Use Code, the affirmations of compliance for medical devices (such as the registration, listing, and premarket numbers) are optional.

Additional information on EUA

[Umbrella EUA for Surgical Masks](#)

[N95 and Other Respirators EUAs](#)

[Umbrella EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators \(FFRs\) Manufactured in China](#)

[Face Shields and Other Barrier](#)

Key stakeholders in the US regulatory process

Differently from the EU where a company is obliged to obtain authorization through a notified body, in the US a company must obtain authorization from the FDA. Below are key stakeholders in the US regulatory process.

1. Association for the Advancement of Medical Instrumentation (AAMI)

AAMI is providing curated collection of resources to assist the health technology field. AAMI has collected a broad variation of important information for manufacturers of PPE and other medical equipment including regulatory standard requirements in the US, design guidelines, guidance on materials and others.

More information can be found at:

[AAMI: Coronavirus Resources from the Field](#)

2. The American National Standards Institute (ANSI)

The American National Standards Institute (ANSI) is a "private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. Founded in 1918, the Institute works in close collaboration with stakeholders from industry and government to identify and develop standards- and conformance-based solutions to national and global priorities.

"ANSI is not itself a standards developing organization. Rather, the Institute provides a framework for fair standards development and quality conformity assessment systems and continually works to safeguard their integrity. And as a neutral venue for coordination of standards-based solutions, the Institute brings together private- and public-sector experts and stakeholders to initiate collaborative standardization activities that respond to national priorities."⁸⁷

More information can be found at:

[ANSI: ANSI Resources Center for COVID-19 \(https://www.ansi.org/resource-center/covid-19\)](#)

[ANSI: ANSI Standards for COVID-19 \(https://www.ansi.org/news-and-events/standards-news/all-news/2020/04/ansi-expands-standards-portal-for-covid19-crisis-to-include-iec-standards-06\)](#)

3. American Society for Testing and Materials (ASTM)

The American Society for Testing and Materials (ASTM) International, is "an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services"⁸⁸

More information can be found at:

[ASTM: ASTM Standards & COVID-19 \(https://www.astm.org/COVID-19/\)](#)

[ASTM: ASTM Standards and Publications \(https://www.astm.org/Standard/standards-and-publications.html\)](#)

[ASTM: ASTM Frequently Asked Questions \(https://www.astm.org/FAQ/#what\)](#)

4. The Centers for Disease Control and Prevention (CDC)

The Centers for Disease Control and Prevention (CDC) is a "national public health institute in the United States. Its main goal is to protect public health and safety through the control and prevention of disease, injury, and disability in the US and internationally. The CDC focuses national attention on developing and applying disease control and prevention. It especially focuses its attention on infectious disease, food borne pathogens, environmental health, occupational safety and health, health promotion, injury prevention and educational activities designed to improve the health of United States citizens. The CDC also conducts research and provides information on non-infectious diseases, such as obesity and diabetes, and is a founding member of the International Association of National Public Health Institutes.

"CDC is working closely with international partners to respond to the coronavirus (COVID-19) pandemic. CDC provides technical assistance to help other countries increase their ability to prevent, detect, and respond to health threats, including COVID-19."⁸⁹

More information can be found at:

[CDC: PPE at The National Institute for Occupational Safety and Health\(NIOSH\) \(https://www.cdc.gov/niosh/ppe/default.html\)](#)

[CDC: Code of Federal Regulations \(CFR\) \(https://www.cdc.gov/niosh/regulations.html\)](#)

[CDC: NIOSH Personal Protective Equipment \(PPE\) Information \(https://www.cdc.gov/PPEInfo\)](#)

[CDC: Strategies for Optimizing PPE Supplies \(https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html\)](#)

5. Food and Drug Administration (FDA)

The FDA is "responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

"FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

"Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification- also called PMN or 510(k). This allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories. Thus, "new" devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified. Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use."⁹⁰

More information can be found at:

FDA: [FDA Registration and Listing of Medical Devices during the COVID-19 Pandemic](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/registration-and-listing-medical-devices-during-covid-19-pandemic#regist) (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/registration-and-listing-medical-devices-during-covid-19-pandemic#regist)

FDA: [FDA 510\(k\) Clearances](https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances) (https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances)

FDA: [FDA Combating COVID-19 with Medical Devices](https://www.fda.gov/media/136702/download) (https://www.fda.gov/media/136702/download)

FDA: [Information for Filing Personal Protective Equipment and Medical Devices During COVID-19](https://www.fda.gov/industry/importing-covid-19-supplies/information-filing-personal-protective-equipment-and-medical-devices-during-covid-19) (https://www.fda.gov/industry/importing-covid-19-supplies/information-filing-personal-protective-equipment-and-medical-devices-during-covid-19)

Chinese market

All products sold in China are required to meet Chinese quality requirements. Depending on the classification of the PPE (please see table below), the level of standard requirements may differ. For example, Class I and Class II most of the times do not require clinical studies. However, all classes require a quality management.³¹

Classification of medical devices

Medical devices for the Chinese market are categorised into three different classes by the National Medical Products Administration (NMPA), formerly the China Food and Drug Administration (CFDA). Requirements for approval depend on the class.³²

- For Class I devices, safety and effectiveness can typically be ensured through documentation, so product tests and clinical trials in China are not usually required.
- For Class II devices, safety and effectiveness can be ensured through documentation and product testing. Some Class II devices may require clinical trials.
- Class III devices, which are mostly devices implanted into the human body or used for life support or sustenance, and which can therefore pose a potential risk to the human body, are strictly controlled by mandated tests and clinical trials to ensure their safety and effectiveness.

Classification	Quality management	Country of origin approval	Product test	Clinical studies	Competent authority
Class I	Required	Required	Rarely necessary	Not necessary	City Level
Class II	Required	Required	Required	Rarely necessary	Provincial level
Class III	Required	Required	Required	Required	Nation Level

More information can be found at:

CFDA: [What is CFDA?](http://www.sfdachina.com/info/50-1.htm) (http://www.sfdachina.com/info/50-1.htm)

CFDA: [China CFDA/SFDA Registration](https://www.sfdachina.com/infosort/1_1.htm) (https://www.sfdachina.com/infosort/1_1.htm)

NMPA: [National Medical Products Administration \(NMPA\)](http://english.nmpa.gov.cn/) (http://english.nmpa.gov.cn/)

GB China National Standards Service Center: [Chinese GB Standards Search and Class Index](https://www.gbstandards.org/index.asp) (https://www.gbstandards.org/index.asp)

Emergo by UL Global™ [China NMPA Regulatory Approval Process for Medical Devices](https://www.emergobyul.com/resources/china-process-chart) (https://www.emergobyul.com/resources/china-process-chart)

Notified Bodies for the Chinese market

The China National Accreditation Service for Conformity Assessment (CNAS) is the national accreditation body of China responsible for the accreditation of all laboratories, certification bodies and inspection bodies. The test reports issued are internationally mutually recognized.³³

The China Metrology Accreditation (CMA) examines the testing ability and reliability of testing organizations such as commercial and government laboratories.

Russian market

Russia's State Standards (GOST) were originally developed by the government of the Soviet Union as part of its national standardization strategy.

Central registration

In the Russian Federation, all medical devices for use for diagnostic and therapeutic purposes must be registered in Moscow, at the central department of the Federal Service on Surveillance in Healthcare and Social Development. The certificate must indicate the name of the producer, the name of the device, the intended use, the class of potential risk to the patient and any similar information.³⁴

If the medical device is a complex unit, consisting of multiple components (modules), the certificate of registration has to be accompanied by documents identifying all the components and any accessories with which the device is supplied. If the components (modules) are produced by different manufacturers and marketed under their own brand, "the certificate of registration used for each component. In this case, before proceeding with the registration is advisable to verify that the component in question has not already been registered. To do this simply go to National Directory of medical devices and do a search. The certificate of registration of the component should be made payable to producer, who must provide a letter of consent to use of its product by the applicant for registration."³⁵

Registration is followed by the declaration of conformity GOST-R, and where required a customs union hygienic registration certificate. If the medical device incorporates weighing or measuring instruments such as gauges, thermometers or sensors, a metrological certificate must also be obtained.³⁶

Additional information

More information on Russian standards and medical device registration can be found at the following links:

RUStandard: [What is the GOST R certificate and When it is required?](http://www.rustandard.com/en/gost-r-certificate.html) (http://www.rustandard.com/en/gost-r-certificate.html)

GOST-R Info: [GOST-R Certifications](https://www.gost-r.info/) (https://www.gost-r.info/)

TÜV-SÜD: [Lists of products subject to GOST-R mandatory certification](https://www.tuv-sud.cn/cn-en/activity/focus-topics/russian-national-certification-gost-r/gost-r-certificate) (https://www.tuv-sud.cn/cn-en/activity/focus-topics/russian-national-certification-gost-r/gost-r-certificate)

Certification Quality Conformity sp. z o.o.: [List of GOST-R standards identical to the EN standards](https://www.certificator.eu/en/certification-handbook/list-of-gost-r-standards-identical-to-en-standards.html) (https://www.certificator.eu/en/certification-handbook/list-of-gost-r-standards-identical-to-en-standards.html)

RUStandard: [Medical Device Registration in Russia](http://www.rustandard.com/en/medical-device-registration-in-russia.html) (http://www.rustandard.com/en/medical-device-registration-in-russia.html)

CHAPTER 5: Guidance on Labour Force Capacity Building and Skills Requirements for PPE Manufacturing

In this chapter, the vital issue of safety and health measures are defined for the labour force on the premise of the manufacturing facilities and how to establish a structured system on how to keep the highest standard of health and safety. First, the definitions and importance of health and safety measures are described as per WHO definitions. Secondly, the safety and health management systems defined by the International Labour Organization (ILO) is outlined. Thirdly, a guideline on how to best implement such measures are provided. Lastly, a description on how the safety and health measures are maintained within the organization is described.

The importance of safety and health measures

Restoring global health remains the priority, but the strict measures required are resulting in massive economic and social shocks. As lockdown, quarantine, physical distancing, and other isolation measures intended to suppress transmission continue, the global economy has plunged into a recession. The harmful effects of this pandemic will not be distributed equally.

To prevent the spread of the virus and to ensure distancing, many businesses were temporarily shut down and many employed people confined to their homes. These measures are important in all sectors and industries – and not least the manufacture of PPE. Production lines must remain hygienic at the most sophisticated level and educating employees to implement standards of cleanliness on a daily basis is vital.⁹⁷ The COVID-19 pandemic once again recalled the importance of occupational safety and health (OSH), as defined by The World Health Organization (WHO):

"deals with all aspects of health and safety in the workplace and has a strong focus on primary prevention of hazards."⁹⁸

Health has been defined as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." Occupational health is the multidisciplinary field of healthcare concerned with enabling an individual to undertake their occupation in the way that causes least harm to their health. It is aligned with the promotion of health and safety at work, which is concerned with preventing harm from hazards in the workplace.

Occupational safety and health management systems – ILO-OSH 2001

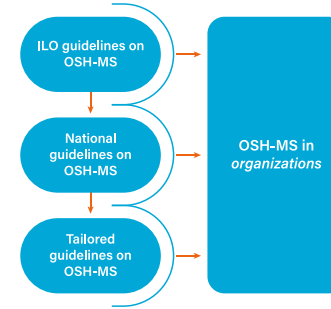
The guidelines for occupational safety and health (OSH) management established by the International Labour Organization (ILO) call for coherent policies to protect workers from occupational hazards and risks while improving productivity. They present practical approaches and tools for assisting organizations, competent national institutions, employers, workers and other partners in establishing, implementing and improving occupational safety and health management systems, with the aim of reducing work-related injuries, ill health, diseases, incidents and deaths.

The guidelines may be applied on two levels – national and organisational.⁹⁹

At the national level, they provide for the establishment of a national framework for OSH management systems, preferably supported by national laws and regulations. They also provide precise information on developing voluntary arrangements to strengthen compliance with regulations and standards, which, in turn, lead to continual improvement of OSH performance.

At national level, the guidelines should:

- Be used to establish a national framework for OSH management systems, preferably supported by national laws and regulations.
- Provide guidance for the development of voluntary arrangements to strengthen compliance with regulations and standards leading to continual improvement in OSH performance.
- Provide guidance on the development of both national and tailored guidelines on OSH management systems to respond appropriately to the real needs of organizations, according to their size and the nature of their activities.



At the organizational level, the Guidelines encourage the integration of OSH management system elements as an important component of overall policy and management arrangements. Organizations, employers, owners, managerial staff, workers and their representatives are motivated in applying appropriate OSH management principles and methods to improve OSH performance.

At the level of the organization, the guidelines are intended to:

- Provide guidance regarding the integration of OSH management system elements in the organization as a component of policy and management arrangements.
- Motivate all members of the organization, particularly employers, owners, managerial staff, workers, and their representatives, in applying appropriate OSH management principles and methods to continually improve OSH performance.

How to implement OHS management systems

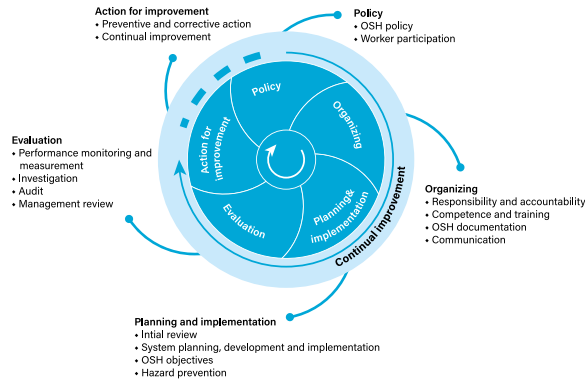
The implementation of an OHS management system is a strategic and operational decision for an organization. The success of the OHS management system depends on leadership, commitment and participation from all levels and functions of the organization, in other words it is important to establish the importance of high standards in all parts of the organization.

The implementation and maintenance of an OHS management system, its effectiveness, and its ability to achieve its intended outcomes are dependent on a number of key factors, which may include:¹⁰⁰

- top management leadership, commitment, responsibilities, and accountability.
 - top management developing, leading, and promoting a culture in the organization that supports the intended outcomes of the OHS management system.
 - communication.
 - consultation and participation of workers, and, where they exist, workers' representatives.
 - allocation of the necessary resources to maintain the system.
 - OHS policies which are compatible with the overall strategic objectives and direction of the organization.
 - effective process(es) for identifying hazards, controlling OHS risks and taking advantage of OHS opportunities.
 - continual performance evaluation and monitoring of the OHS management system to improve OHS performance.
 - integration of the OHS management system into the organization's business processes.
 - OHS objectives that align with the OHS policy and take into account the organization's hazards, OHS risks and OHS opportunities.
 - compliance with legal requirements and other requirements.
- See also Chapter 3 for further information on ISO standards.

The OSH management system in the organization

Occupational safety and health, including compliance with the OSH requirements pursuant to national laws and regulations, are the responsibility and duty of the employer. The employer should show strong leadership and commitment to OSH activities in the organization and make appropriate arrangements for the establishment of an OSH management system. The system should contain the main elements of policy, organizing, planning and implementation, evaluation, and action for improvement.¹⁰¹



Additional information on COVID-19 and the labour force

Eurostat: [Labour market in the light of the COVID-19 Pandemic](https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Labour_market_in_the_light_of_the_COVID_19_pandemic_-_quarterly_statistics#:~:text=The%20consequences%20on%20the%20labour,working%20hours%20or%20simply%20stopped) (https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Labour_market_in_the_light_of_the_COVID_19_pandemic_-_quarterly_statistics#:~:text=The%20consequences%20on%20the%20labour,working%20hours%20or%20simply%20stopped)

ILO: [COVID-19 Impact on Labour Market Statistics](https://ilostat.ilo.org/topics/covid-19/covid-19-impact-on-labour-market-statistics/) (https://ilostat.ilo.org/topics/covid-19/covid-19-impact-on-labour-market-statistics/)

ILO: [COVID-19 Stimulating the Economy and Employment](https://www.ilo.org/global/about-the-ilo/newsroom/news/WCMS_743036/lang--en/index.htm) (https://www.ilo.org/global/about-the-ilo/newsroom/news/WCMS_743036/lang--en/index.htm)

Statistics Netherlands (CBS): [COVID-19 Impact on Labour and Income](https://www.cbs.nl/en-gb/dossier/coronavirus-crisis-cbs-figures/covid-19-impact-on-labour-and-income) (https://www.cbs.nl/en-gb/dossier/coronavirus-crisis-cbs-figures/covid-19-impact-on-labour-and-income)

UN Women: [COVID-19 Economic Impacts on Women](https://www.unwomen.org/en/news/stories/2020/9/feature-covid-19-economic-impacts-on-women?gclid=EALalQobChMlLb16duk7AIVz-J3Ch0gNgONEAAYAAEgJQnVD_BwE) (https://www.unwomen.org/en/news/stories/2020/9/feature-covid-19-economic-impacts-on-women?gclid=EALalQobChMlLb16duk7AIVz-J3Ch0gNgONEAAYAAEgJQnVD_BwE)

ILO: [COVID-19 Impact on Child Labour and Forced Labour](https://www.ilo.org/global/about-the-ilo/how-the-ilo-works/flagships/pec-plus/WCMS_745287/lang--en/index.htm) (https://www.ilo.org/global/about-the-ilo/how-the-ilo-works/flagships/pec-plus/WCMS_745287/lang--en/index.htm)

UNCTAD: [COVID-19 Impact on Global Trade](https://unctad.org/system/files/official-document/ditcinf2020d1.pdf) (https://unctad.org/system/files/official-document/ditcinf2020d1.pdf)

World Bank: [COVID-19 Impact on Labor Market Outcomes: Lessons from past economic crises](https://blogs.worldbank.org/education/impact-covid-19-labor-market-outcomes-lessons-past-economic-crises) (https://blogs.worldbank.org/education/impact-covid-19-labor-market-outcomes-lessons-past-economic-crises)

WHO: [WHO Coronavirus Disease \(COVID-19\) Dashboard](https://covid19.who.int/?gclid=EALalQobChMliq6SnbzA7AIViwCiAx0xNQqQEAAYASAAEgJlDP_BwE) (https://covid19.who.int/?gclid=EALalQobChMliq6SnbzA7AIViwCiAx0xNQqQEAAYASAAEgJlDP_BwE)

CHAPTER 6: Global PPE Market and Potential Bottlenecks and Risks due to COVID-19

Having established the material and equipment requirements, the standards for export markets, and the importance of occupational safety and health measures within the manufacturing facility in previous chapters, this chapter will focus on the global market, the opportunities for export to foreign markets, as well as the potential bottlenecks and risks that come with it.

First, the global market for PPE will be defined with the current and future forecasted size of the market. The potential drivers for the large growth of the PPE market will also be described in this part of the chapter. Secondly, the potential bottlenecks for production and export of PPE in the era of COVID-19 will be outlined. Lastly, the chapter ends with potential solutions for how to resolve these bottlenecks and how to mitigate the risks involved.

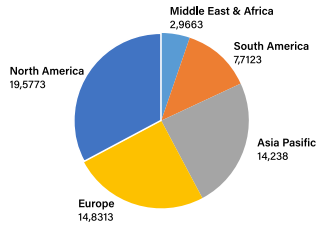
The global market for PPE

The size of the global personal protective equipment market was estimated at around \$58 billion in 2020, between 2016 and 2020, the compound annual rate of increase in the global market for PPE was 6.5% and has risen to approximately \$40 Billion to \$58 Billion. In contrast, the World Health Organization projected that PPE supplies must increase by 40% monthly to deal effectively the COVID-19 pandemic.¹⁰² The market is expected to grow further, at a compound annual growth rate of 9.6% between 2020 and 2027 to reach \$93.61 billion. Expectations of strong demand growth are closely linked to the existing and anticipated impact of the pandemic.^{103 104}

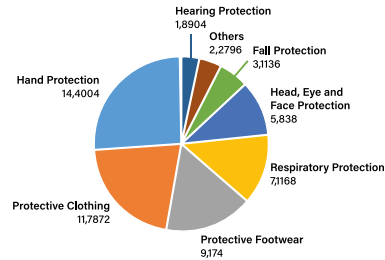
North America and Europe accounted for approximately 58% global revenue share within the PPE market, primarily due to the demand for high-utility protective equipment across industries such as automotive, oil & gas, refining and metal manufacturing.¹⁰⁵ To all this, must be added the demand for private and professional use in the wake of COVID-19. The explosion in the demand for PPE caused by the pandemic has led to a shortage of supply, to which manufacturers are striving to respond. Many countries are struggling to supply their healthcare personnel with the necessary protective equipment, an issue that is still trying to be resolved by suppliers across the globe. Among other issues driving this demand constraint is the restrictions that many countries have imposed. These and other bottlenecks are discussed later in this chapter.

The total demand for PPE in USD \$19.58B for North America, \$14.83B for Europe, \$14.24B for Asia Pacific, \$7.71B for South America, and \$2.97B for Middle East & Africa based on the most recent data as of 2019. Furthermore, the breakdown of products relevant to this guideline account for approximately 70% of the total market size of PPE. Hand protection account of \$14.4B, protective clothing for \$11.79B, respiratory protection for \$7.12B, and head, eye, & face protection for \$5.84B.^{106 107}

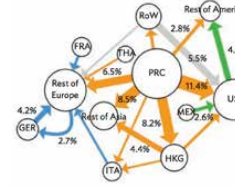
PPE Market Size by Region in Billion USD



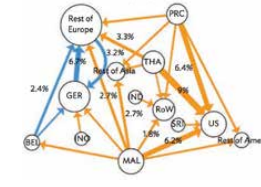
PPE Market Size by Product in Billion USD



e. HS 900490 Including Protective Goggles: Spectacles, goggles, and the like; (other than sunglasses) corrective, protective, or other



f. HS 401511 Including Surgical Gloves: Rubber; vulcanized (other than hard rubber), surgical gloves

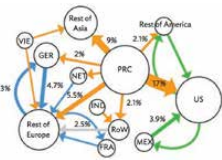


← exports from Americas ← exports from Asia ← exports from Europe ← exports from the rest of the world

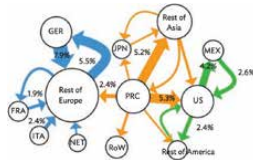
Global trade network of PPE

Based on analysis of trade networks on specific PPE products including surgical masks, respirators, surgical gowns, protective suits, goggles and gloves, it is clear that Peoples Republic of China (PRC) play a key role in the production and export of PPE across a broad span of products, while the US and Europe are net importers.¹⁰⁸

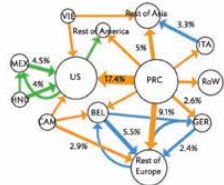
a. HS 630790 Including Surgical Masks: Textiles; made up articles (including dress patterns), not elsewhere classified (n.e.c.)



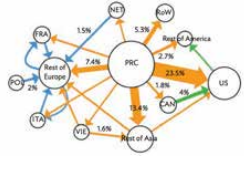
b. HS 392690 Including Respirators: Plastics; other articles n.e.c.



c. HS 621010 Including Surgical Gowns: Garments; of felt or nonwoven (not knitted or crocheted)



d. HS 392620 Including Protective Suits: Plastics; articles of apparel and clothing accessories (including gloves, mittens, and mitts)



Key drivers and opportunities in the global healthcare PPE market

The sudden outbreak of COVID-19 is the key factor driving the growth of the global PPE market. The World Health Organization (WHO) has urged all PPE manufacturers globally to increase production immediately.¹⁰⁹ To be more specific:

- 1) Globally, the demand for healthcare services is rising due to the increase in population, chronic illnesses, and accidents. The rising number of patients adds to the risk of healthcare workers becoming infected and PPE is therefore utilized extensively in the sector as well as by the general population.
- 2) The recent outbreak of COVID-19 has significantly accelerated the demand for PPE. All countries are experiencing shortages of PPE, and their demand is at an all-time high. An increase in the number of surgical procedures around the world is expected to enlarge the global healthcare PPE market further in the years ahead.
- 3) There is a significant gap between demand and supply which offers considerable opportunities for manufacturers to enter the market. Several countries have utilized their emergency resources and are set to replenish their stocks. This is likely to provide manufacturers with major opportunities.

The above information draws on:

Transparency Market Research **Healthcare PPE Market: Global Industry Analysis, Size, Share, Growth, Trends, and Forecast, 2020 - 2030** (<https://www.transparencymarketresearch.com/healthcare-ppe-market.html>)

In addition to the above source, information on international trade and the global PPE/healthcare PPE market can be found at the following links:

Export Genius: **Global Import and Export Data** (<https://www.exportgenius.in/>)

Market Watch: **Global PPE Market Size** (<https://www.marketwatch.com/press-release/global-personal-protective-equipment-ppe-market-size-share-2020-industry-evolution-to-2024-by-growth-insight-key-development-trends-and-forecast-by-market-reports-world-2020-09-22>)

Statista: **Value of the global PPE market 2019-2027** (<https://www.statista.com/statistics/711286/value-of-the-global-ppe-market/>)

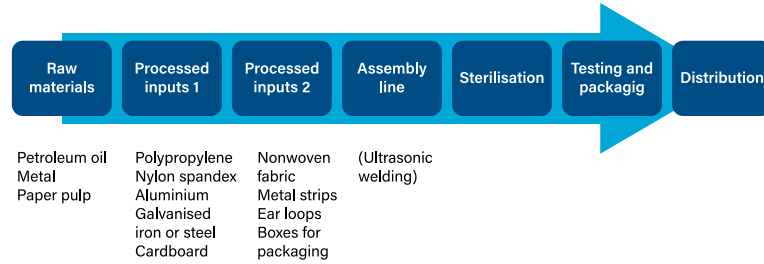
Grand View Research: **Personal Protective Equipment Market Size, Share & Trends Analysis Report 2020 - 2027** (<https://www.grandviewresearch.com/industry-analysis/personal-protective-equipment-ppe-market>)

Bottlenecks within the value chain of PPE

Below, the major bottlenecks that has emerged due to demand shock and production restrictions due to lockdown and import of goods and services, within the PPE value chain will be described. First, the aspect of providing key materials for the manufacturing of PPE is defined. Then, both domestic and international distribution has been and continues to be an obstacle for PPE manufacturers. Lastly, the issue of export restrictions are described.

Specialised inputs can be in short supply and are hard to manufacture quickly

The face mask value chain has been outlined here in order to explain the bottlenecks faced in the production and distribution of PPE more clearly. The face mask value chain is illustrated below, based on an OECD report.¹⁰ Besides the non-woven materials, the main raw materials for the manufacture of non-woven PPE include oil and metal, used for the nose bands and ear loops, and sometimes other textile materials such as cotton. In addition, paper pulp from the forestry industry is needed for cardboard packaging. The main bottleneck in the value chain in terms of inputs has been non-woven fabric manufactured with polypropylene.



According to the OECD report: "Polypropylene (PP) is one of the most commonly produced plastics in the world and, as a polymer derived from oil, can be easily supplied (although dependent on oil prices and access to oil). Manufacture of PP non-woven fabric is also quite widespread, as it is used in baby diapers, feminine hygiene products, and disposable wipes, as well as in the automotive and construction industries. However, PP electret melt-blown non-woven is a specialised fabric, produced by a limited number of companies globally due to the high initial investment required in heavy machinery, such as hoppers, extruders and melt spinning systems. For this reason, it has been more difficult to increase supply during the crisis, or to find companies that can switch to this production within a reasonable time and without massive investment."¹¹

Often, manufacturers buy non-woven fabric ready-made and just weld the layers (This is particularly true of those manufacturers who have switched to mask production during the crisis). The shortage of PP non-woven fabric remains a challenge for new potential manufacturers of PPE and does seem to be holding back some.

Ultrasonic welding is used in a variety of other industries such as the automotive industry, which makes the raw materials for its process more accessible. Hence the rest of the value chain has been less disrupted during the COVID-19 pandemic. However, specialised machines are still needed at the assembly stage.

Distribution has also been a bottleneck – including domestically

During COVID-19, the global face mask value chain has also encountered a bottleneck at the distribution stage, due to the complications of transport and logistics. This bottleneck was especially challenging in the early days of the pandemic. It remains an issue due to the export restrictions (see below) imposed by countries that fear for their domestic supplies of PPE.¹²

As the OECD report indicates:

"First, in terms of the international supply chain, several countries have put in place export restrictions or equivalent measures (discussed further below), or introduced new authorization or certification procedures, which can cause delays in exports.

"Second, domestic transport and logistics infrastructure, and domestic distribution, have also been disrupted by COVID-19. While varying across countries, including due to the extent of preparedness of the health infrastructure, masks have sometimes been in short supply, not because of a shortage of goods but because they were not reaching health workers. This, essentially domestic, downstream part of the value chain can be as disrupted as the more international part upstream. Here, the main challenge has been in assessing needs in real-time, and prioritising deliveries and anticipating changes at a time when the whole health system is under stress. In addition, the shortage of masks in some countries has led to thefts and the hijacking of some shipments."¹³

More information on value chain bottlenecks can be found at the following links:

US National Library of Medicine/National Institutes of Health: [What does the COVID-19 pandemic teach us about global value chains?](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7360894/) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7360894/)

Asian Development Bank: [COVID-19: Supply Chains, Bottlenecks, and Policy Implications](https://www.adb.org/sites/default/files/publication/579121/ppe-covid-19-supply-chains-bottlenecks-policy.pdf) (https://www.adb.org/sites/default/files/publication/579121/ppe-covid-19-supply-chains-bottlenecks-policy.pdf)

International Trade Centre: [COVID-19 temporary export measures](https://www.macmap.org/covid19) (https://www.macmap.org/covid19)

Many countries have also introduced restrictions on the export of masks and other PPE

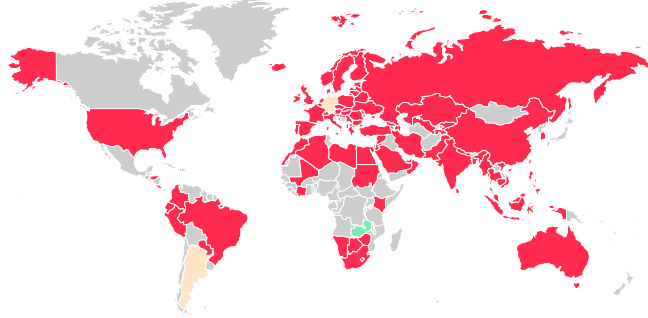
As noted by the International Trade Centre, "In order to address domestic shortages of masks, many countries have put in place restrictions on exports or equivalent measures such as the compulsory purchase by governments of all available stocks."¹⁴

Taiwan was the first economy to ban exports of masks on 24 January 2020¹⁵ and many others have subsequently introduced export bans. These export bans or compulsory purchases are generally temporary, with some already removed. Countries banning exports are not all producers or exporters of masks, non-producers can be motivated by a desire to prevent hoarding or to avoid the export of masks already imported to be sold at a higher price abroad.

While some EU countries producing masks have enacted export bans, an EU-wide regulation was adopted on the 15th March 2020 introducing export authorizations.¹⁶ Exports are not banned, but the needs of EU countries must be taken into account before exports are authorized. A similar system has been implemented in the United States since 10 April 2020, with a temporary rule from the Federal Emergency Management Agency banning exports of masks¹⁷, but providing a list of exemptions which, for example, covers pre-existing commercial relationships. Export licenses or permits for face masks have also been introduced in other countries. Below is a map indicating the temporary trade restrictions based on countries (map was last visited on the 26th of November 2020).¹⁸

COVID-19 Temporary Export Measures

Affected products include personal protection equipment(e.g.masks, gloves), pharma products, hand sanitizer, food and certain other products



Temporary Export Measures

- Export restrictions/bans (93 countries)
- Export liberalisations (2 countries)
- Export restrictions and liberalisations (2 countries)
- None (137 countries)

Source: ITC Market Access Map (www.macmap.org) based on media reports and official legislations © Natural Earth

Export restrictions have three consequences: First, they prevent some countries with no production capacity from gaining access to masks. Second, they can backfire when countries holding masks need more, or need to import other essential medical supplies (or inputs to manufacture masks). Export licensing and authorization procedures may not only discourage exports but also delay trade when exports are approved. This stands in contradiction to the emergency nature of the need – which is generally also one of the criteria for authorizing exports. Third, export restrictions push prices up and foster illegal activities (black markets and scams).

Export restrictions can also create uncertainties that impact the investment strategies of manufacturers. In China, several of the main producers of masks are foreign-owned firms. Manufacturers of masks generally prefer to locate their production facilities close to the consumers to build robust supply chains. For example, before the COVID-19 crisis, 3M already had a strategy based on local supply in Asia. Export restrictions could discourage these foreign companies from investing, denying the recipient country the benefits of foreign capital and know-how for the creation of local capacity in the production of medical supplies.¹⁹

More information related to export restrictions can be found at the following links:

International Trade Centre: [COVID-19 Temporary Export Measures](https://www.macmap.org/covid19) (<https://www.macmap.org/covid19>)

Asian Development Bank: [COVID-19: Supply Chains, Bottlenecks, and Policy Implications](https://www.adb.org/sites/default/files/publication/579121/ppe-covid-19-supply-chains-bottlenecks-policy.pdf) (<https://www.adb.org/sites/default/files/publication/579121/ppe-covid-19-supply-chains-bottlenecks-policy.pdf>)

World Bank: [Removing regulatory bottlenecks to the supply of COVID-19 products and services](https://blogs.worldbank.org/psd/removing-regulatory-bottlenecks-supply-covid-19-products-and-services) (<https://blogs.worldbank.org/psd/removing-regulatory-bottlenecks-supply-covid-19-products-and-services>)

IDH Sustainable Trade Initiative: [Supplying Personal Protective Equipment \(PPE Dashboard\)](https://www.ppedashboard.org/en) (<https://www.ppedashboard.org/en>)

Resolving bottlenecks

The OECD report on the manufacture of PPE and on bottlenecks within manufacturing notes that "Countries have been implementing measures to ramp up production capacity. Many garment factories and non-medical firms are shifting their production lines to manufacture face masks, responding to unprecedented demand triggered by the COVID-19 pandemic. This reminds us that businesses can adapt quickly to market changes—but only if procedures and approvals are simple enough that they can easily repurpose their activities."²⁰

Many governments have taken regulatory measures to improve the supply of personal protective equipment and medical equipment. These range from fast-tracking approvals for the manufacture and import of PPE to temporarily realigning certification requirements for drugs and equipment. There is also an ongoing effort to facilitate telemedicine.

Many of these measures are temporary, but they serve as examples of how governments can facilitate business activity by simplifying the requirements for starting, conducting, or repurposing it. Both to support COVID-19 crisis management now and the recovery phase that follows, governments—particularly in developing countries—should reconsider their broader regulatory requirements to remove any unnecessary barriers for business operations while still safeguarding public goods like health and the environment.

CHAPTER 7: Financial Assessment of Costs for Manufacturing PPE

In order to assist potential PPE manufacturing in determining the costs, fixed and variable, involved in setting up and running a production facility, this chapter draw upon a tool developed by the International Finance Corporation (IFC).

The chapter first defines how the IFC cost calculator can assist the manufacturer with determining capital expenditure (CapEx), working capital, and revenue & EBIT (Earning before interest & tax) for a PPE production line. Secondly, the definitions within the tool are defined. Thirdly, an example of a Turkish manufacturer of PPE is provided. Fourth, a generic example of a mask manufacturing line is outlined. Lastly, the chapter reflects on the plausibility of setting up a PPE manufacturing facility at this stage of the pandemic.

PPE manufacturing cost calculator

When setting up a manufacturing facility, it is important to make an analysis of the expected costs and the revenue of a production line over a given time. However, these can be difficult to calculate for PPE manufacturing, especially if the manufacturer comes from a different industry, such as textiles. To assist the manufacturer in this analysis, the IFC has created a template model for determining the required working capital needs, CapEx needed for production lines, the EBIT and the revenue from the expected production. As a guideline, the IFC estimates that an automatic production line with capacity of 100 pieces per minute will cost in the range of USD50,000-USD100,000.²¹

Below is an example of these calculations. The spreadsheet is accessible here or at https://www.ifc.org/wps/wcm/connect/industry_ext_content/ifc_external_corporate_site/manufacturing/events/webinar_how+to+start+ppe+production.

Yellow Cells = input your data	Medical/Surgical Mask	Respirator	Isolation Gown	Surgical Gown
Green Cells = protected data				
Production target (pieces/month)	1500.000	1.500.000	200.000	200.000
Standard minutes (S.A.M. per piece)	1,20	1,00	8,00	14,00
Efficiency	%80	%80	%80	%80
Production with Cut & Sew Machinery				
Number of operators	195	163	174	304
Number of new sewing machines	45	20	100	100
Number of new spreading machines	2	2	2	2
Number of new automatic cutters	1	1	1	1
Production with Automatic Machinery				
Production per line (pieces/month)	864.000	518.400		
Number of production lines	2	3		
Number of operators	20	30		
Costing Parameters				
Sales price (\$/piece)	0,25	0,30	2,50	3,50
Fabric cost (\$/piece)	0,15	0,22	1,55	2,20
Other materials (\$/piece)	0,01	0,02	0,40	0,40
Direct labor cost (\$/person/month)	250,00	250,00	250,00	250,00
Working Capital Days				
Inventory days	90	90	90	90
Payable days	0	0	0	0
Receivable days	45	45	45	45

Yellow Cells = input your data	Medical/Surgical Mask	Respirator	Isolation Gown	Surgical Gown	TOTAL
Green Cells = protected data					
CUT & SEW PRODUCTION	\$	\$	\$	\$	\$
Capital Expenditures					
Cut & Sew machinery	647.500	560.000	840.000	840.000	2.887.500
Other machinery (lab equipment, etc.)	30.000	30.000	30.000	30.000	120.000
Line set up, training, sampling, testing, other start-up costs	40.000	40.000	40.000	40.000	160.000
Land, building, contingency					-
TOTAL	717.500	630.000	910.000	910.000	3.167.500

Yellow Cells = input your data	Medical/Surgical Mask	Respirator	Isolation Gown	Surgical Gown	TOTAL
Green Cells = protected data					
Working Capital					
Inventory	660.000	990.000	1.072.500	1.430.000	4.152.500
Payables	-	-	-	-	-
Receivables	515.625	618.750	687.500	962.500	2.784.375
TOTAL	1.175.625	1.608.750	1.760.000	2.392.500	6.936.875
Revenue					
Sales (\$/year)	4.125.000	4.950.000	5.500.000	7.700.000	22.275.000
Materials (\$/year)	2.640.000	3.960.000	4.290.000	5.720.000	16.610.000
Direct labor & production overheads (\$/year)	805.664	671.387	716.146	1.253.255	3.446.452
Other operating costs (sales, administration, etc.)	206.250	247.500	275.000	385.000	1.113.750
Depreciation (\$/year)	71.750	63.000	91.000	91.000	316.750
EBIT (Earnings before interest & tax) \$/year	401.336	8.113	127.854	250.745	788.048
AUTOMATIC PRODUCTION	\$	\$	\$	\$	\$
Capital Expenditures					
Automatic machinery	300.000	300.000	-	-	600.000
Other machinery (lab equipment, etc.)	30.000	30.000			60.000
Line set up, training, sampling, testing, other start-up costs	40.000	40.000			80.000
Land, building, contingency					-
TOTAL	370.000	370.000	-	-	740.000
Working Capital					
Inventory	660.000	990.000	-	-	1.650.000
Payables	-	-	-	-	-
Receivables	515.625	618.750	-	-	1.134.375
TOTAL	1.175.625	1.608.750	-	-	2.784.375
Revenue					
Sales (\$/year)	4.125.000	4.950.000	-	-	9.075.000
Materials (\$/year)	2.640.000	3.960.000	-	-	6.600.000
Direct labor & overheads (\$/year)	110.000	165.000	-	-	275.000
Other operating costs (sales, administration, etc.)	206.250	247.500	-	-	453.750
Depreciation (\$/year)	37.000	37.000	-	-	74.000
EBIT (Earnings before interest & tax) \$/year	1.131.750	540.500	-	-	1.672.250

Definitions of the IFC cost calculator

As a guide to how to use this tool, the definitions and calculations of the spreadsheet are further elaborated in the table below.¹²

Assumptions	
Production target	Monthly production target at maximum capacity utilization
Standard minutes (S.A.M)	Number of working minutes per product with 100% performance against international standard.
Efficiency	Efficiency against standard
Number of operators	(Production target x standard minutes)/ (480 daily minutes x 24 working days in one-month x 80% efficiency)
Number of sewing machines	Depends on how many current machines can be used and how many new ones need to be purchased
Number of spreading machines	Depends on production volume
Number of automatic cutters	Depends on production volume
Automatic production per line (pcs/month)	Calculated with 75 pcs/min for surgical mask and 15 pcs/min for respirators.
Number of automatic production lines	Production target / production per line
Number of operators in automatic lines	# of lines x 10 operators
Sales price	Prices in the model originate from UNIFEC tender.
Fabric cost	Consumption (m/piece) * material price (\$/m)
Other materials	Accessories, such as elastic straps etc.
Direct labour cost (\$/person/month)	Direct wages/person/month + benefits
Inventory days	Average number of days for stocking raw materials, work in progress and ready-made products.
Payable days	Number of credit days from suppliers. This is 0 if payable on delivery.
Receivable days	Number of days' credit given to clients.
Capital Expenditure & Working Capital	
Capital expenditure Cut & Sew machinery	# of new sewing machines x \$3,500 + # of spreading machines x \$120,000 + # of computerized cutters x \$250,000
Capital expenditure Automatic machinery	# of lines x \$150,000 for medical/surgical masks, # of lines x \$100,000 for respirators
Capital expenditure Other machinery	Cost of other equipment and machinery (lab equipment, etc.)
Line set up, training, sampling, testing, other start-up costs	Training of operators + ramp up cost including product testing and compliance costs
Capital expenditure land, building, contingency	Cost of building, land, and contingency
Working capital -inventory	(Inventory days / 360 days) * Materials per year
Working capital - payables	(Payable days / 360 days) * Material cost per year
Working capital - receivables	(Receivable days / 360 days) * Sales per annum

Assumptions	
Working capital Total	Inventory - Payables + Receivables
Sales (\$/year)	Monthly production target * sales price * 11 full operating months per year
Materials (\$/year)	Monthly production target * (fabric cost + other material cost) * 11 operating months per year
Direct labor + production overheads (\$/year)	Number of operators * (wages + benefits) * 11 operating months per year * (1.5 or 2) to cover for production overheads
Other operating costs (sales, administration, etc.)	5% of sales
Depreciation (\$/year)	(Machinery + equipment + ramp up)/10 + (Building + contingency)/20
EBIT (Earnings before interest & tax) \$/year	Sales - (materials + direct labor + production overheads + other operating costs + depreciation)

Example of a Turkish manufacturer

An example of a Turkish manufacturer is given below, using the same spreadsheet, complete with assumptions as well as capital expenditure, working capital, and revenue.

Assumptions

Yellow Cells = input your data	Medical/Surgical Mask	Respirator	Isolation Gown	Surgical Gown	Disposable Coverall
Green Cells = protected data					
Production target (pieces/month)	2.000.000	100.000	200.000	200.000	200.000
Standard minutes (S.A.M. per piece)	1,50	1,00	8,00	14,00	14,00
Efficiency	%80	%80	%80	%80	%80
Production with Cut & Sew Machinery					
Number of operators	326	11	174	304	304
Number of new sewing machines	40	20	100	100	100
Number of new spreading machines	2	2	2	2	2
Number of new automatic cutters	20	1	1	1	1
Production with Automatic Machinery					
Production per line (pieces/month)	1.036.800	172.800	500.000	500.000	500.000
Number of production lines	1	1	12	16	24
Number of operators	60	6	50	75	100

Yellow Cells = input your data	Medical/Surgical Mask	Respirator	Isolation Gown	Surgical Gown	Disposable Coverall
Green Cells = protected data					
Costing Parameters					
Sales price (\$/piece)	0,08	1,30	2,50	3,50	3,50
Fabric cost (\$/piece)	0,06	0,22	1,55	2,20	2,20
Other materials (\$/piece)	0,01	0,02	0,40	0,40	0,40
Direct labor cost (\$/person/month)	542,00	542,00	250,00	250,00	250,00
Working Capital Days					
Inventory days	90	90	90	90	90
Payable days	0	0	0	0	0
Receivable days	45	45	45	45	45

Capex, Working Capital, and Revenue

Yellow Cells = input your data	Medical/Surgical Mask	Respirator	Isolation Gown	Surgical Gown	Disposable Coverall	TOTAL
Green Cells = protected data						
CUT & SEW PRODUCTION	\$	\$	\$	\$	\$	\$
Capital Expenditures						
	40 units ultrasonic welding machine and 15 units body machine					
Cut & Sew machinery	2.100.000	112.000	150.000	200.000	250.000	962.000
Other machinery (lab equipment, etc.)	-	-	30.000	30.000	30.000	90.000
Line set up, training, sampling, testing, other start-up costs	50.000	100.000	40.000	40.000	40.000	220.000
Land, building, contingency	150.000	150.000	2.000.000	2.000.000	2.000.000	6.150.000
TOTAL	2.300.000	362.000	2.220.000	2.270.000	2.320.000	7.172.000
Working Capital						
Inventory	2.000.000	-	500.000	600.000	800.000	1.900.000
Payables	400.000	-	50.000	100.000	125.000	275.000
Receivables	-	-	-	-	-	-
TOTAL	1.600.000	-	450.000	500.000	675.000	1.625.000

Yellow Cells = input your data	Medical/Surgical Mask	Respirator	Isolation Gown	Surgical Gown	Disposable Coverall	TOTAL
Green Cells = protected data						
Revenue						
Sales (\$/year)	10.000.000	-	6.000.000	7.500.000	8.500.000	22.000.000
Materials (\$/year)	4.000.000	-	2.500.000	3.000.000	4.000.000	9.500.000
Direct labor & production overheads (\$/year)	2.000.000	-	100.000	150.000	200.000	450.000
Other operating costs (sales, administration, etc.)	1.000.000	-	2.000.000	2.500.000	2.700.000	1.100.000
Depreciation (\$/year)	222.500	28.700	122.000	127.000	132.000	409.700
EBIT (Earnings before interest & tax) \$/year	2.777.500	(28.700)	1.278.000	1.723.000	1.468.000	4.440.300
AUTOMATIC PRODUCTION	\$	\$	\$	\$	\$	\$
Capital Expenditures						
Automatic machinery	900.000	-	250.000	300.000	350.000	900.000
Other machinery (lab equipment, etc.)	30.000	30.000	50.000	75.000	100.000	255.000
Line set up, training, sampling, testing, other start-up costs	40.000	40.000	50.000	75.000	100.000	265.000
Land, building, contingency			2.000.000	2.000.000	2.000.000	6.000.000
TOTAL	970.000	70.000	2.350.000	2.450.000	2.550.000	7.420.000
Working Capital						
Inventory	380.000	40.000	500.000	600.000	800.000	1.940.000
Payables	-	-	50.000	100.000	125.000	275.000
Receivables	-	-	-	-	-	-
TOTAL	380.000	40.000	450.000	500.000	657.000	1.665.000
Revenue						
Sales (\$/year)	2.100.000	-	6.000.000	7.500.000	8.500.000	22.000.000
Materials (\$/year)	800.000	-	2.500.000	3.000.000	4.000.000	9.500.000
Direct labor & overheads (\$/year)	400.000	-	100.000	150.000	200.000	450.000
Other operating costs (sales, administration, etc.)	200.000	-	2.000.000	2.500.000	2.700.000	1.100.000
Depreciation (\$/year)	180.000	7.000	122.000	127.000	132.000	388.000
EBIT (Earnings before interest & tax) \$/year	520.000	(7.000)	1.278.000	1.723.000	1.468.000	4.462.000

Cost of a mask production line

Below is a rough estimate of the fixed and variable costs of a PPE manufacturing facility. However, it is important to note that these can vary greatly depending on the country of production.

One-time input costs (USD, approx.)	
Mask-making machine	90,000
Area / 100K level cleaning workshop (approx. 40m ²)	7,000
Technology learning	300
Continuous input costs (daily) (USD, approx.)	
Raw material	
0.1 tons melt-blown non-woven fabric	6,000
0.2 tons spunbond non-woven fabric	
Ear bands, metal strips	
Manpower	300
Nine people, 8 hours each, full-day production	

NB: The consumption of 0.1 tons of melt-blown non-woven fabric and 0.2 tons of spunbond non-woven fabric per 24 hours is based on the assumption that the weight of the mask material is 30g/m², the size of the mask is about 18cm x 18cm, and the output of a mask-making machine is about 100,000 units per day.¹²³

More information on PPE production costs can be found at the following links:

IFC: [How to start PPE production](https://www.ifc.org/wps/wcm/connect/industry_ext_content/ifc_external_corporate_site/manufacturing/events/webinar_how-to-start+ppe+production) (https://www.ifc.org/wps/wcm/connect/industry_ext_content/ifc_external_corporate_site/manufacturing/events/webinar_how-to-start+ppe+production)

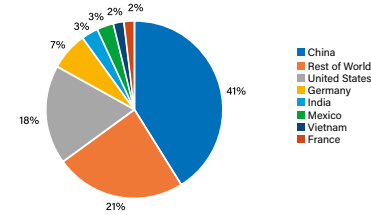
Testex Textiles: [The Common FAQ about the Production, Purchase and Use of Masks: Complete Guide](https://www.testextextile.com/the-common-faq-about-the-production-purchase-and-use-of-masks-complete-guide/) (https://www.testextextile.com/the-common-faq-about-the-production-purchase-and-use-of-masks-complete-guide/)

Testex Textiles: [Is it too Late to Invest Mask Production Line?](https://www.testextextile.com/mask-making-machine-is-it-too-late-to-invest-mask-production-line/) (https://www.testextextile.com/mask-making-machine-is-it-too-late-to-invest-mask-production-line/)

Deciding to invest in a mask production line

The pandemic evolved drastically during the spring of 2020, and while it was expected to fade over the summer, the United States and South America saw big increases in the daily numbers of cases. European countries were expected to have seen the worst, but as of autumn the numbers of daily infections in Europe have reached high levels once again, some countries worse than the first wave of the pandemic, and are not expected to go down immediately during the winter period.¹²⁴

The demand for masks is immense and there is no doubt that if we want to control the spread of the pandemic effectively, the world needs to build a wide range of mask production lines and other PPE manufacturing facilities. China is the largest mask manufacturer in the world, in terms both of melt-blown non-woven fabric and of finished products, accounting for about 50% of global production.¹²⁵ But many other countries have started producing large amounts of PPE.



Note: Estimates based on trade flows observed for HS 630790 and using shares calculated with HS8 and HS10 trade data to identify face masks. Source: UN COMTRADE and ITC Trade Map

Is it too late to invest now?

The case for setting up a production facility is:

- As the pandemic continues to ravage and reappear through a so called "second wave", the demand for PPE continues to stay at a high level and is expected to do so over the coming years. It is estimated that the pandemic will continue to make life difficult throughout the winter period in the northern hemisphere as can be seen on the rise in numbers across the world.¹²⁶
- The gap in mask supply is very large. Global mask production is far from sufficient. Many countries have made the wearing of masks mandatory to various degrees. The demand for PPE is not expected to decline substantially during the postpandemic period either, with an estimated compound annual growth of 20% in facial and surgical masks supply from 2020 to 2025.¹²⁷
- COVID-19 has exposed the vulnerabilities of societies and in order to deal with these issues through further resilience by having PPE and other necessities available if a new pandemic should evolve needs to be addressed.
- The return on investment in a production line is rapid. The cost can be recovered very quickly.

CHAPTER 8: USHAŞ International Health Services Inc.

In this chapter, the important work within the Turkish market for PPE from USHAŞ International Health Services Inc. (USHAŞ) during the COVID-19 pandemic is outlined. Based on the experiences of working with and enabling manufacturers of PPE, USHAŞ has provided valuable insights to this guideline. The chapter will start with defining the establishment of USHAŞ as an institution, then outline the activities and the response of USHAŞ during the pandemic. Lastly, the solutions and lessons learned from the activities of USHAŞ are described.

About USHAŞ

USHAŞ was established as a subsidiary of the Ministry of Health in accordance with Decree Law No. 663, published in the Official Gazette No. 30498 of 3 August 2018. The company became operational on 4 February 2019 with headquarters in Ankara.

All of the shares of USHAŞ belong to the Ministry of Treasury and Finance. However, the rights and powers such as management, representation and inspection are exercised by the Ministry of Health, provided that all financial rights remain with the Ministry of Treasury and Finance and the property rights of the Ministry of Treasury and Finance and its right to dividends are not prejudiced. The assent of the Ministry of Treasury and Finance is required before the USHAŞ operating budget is submitted for the approval of its General Assembly.

USHAŞ activities and exemptions

The activities of USHAŞ listed in Decree Law No. 663 are as follows:

- Promoting the health services and health institutions of Turkey in the international arena, and coordinating, guiding, and supporting information activities,
- Conducting intermediary activities related to international health services, making contracts for international health services on behalf of public and private sector institutions within the framework of the authority given it, and supporting the execution of the contracts entered into,
- Responding to applications for information on international health services, communicating with the relevant authorities for the resolution of complaints and disputes, and identifying problems that parties may face and taking preventive measures,
- Providing information about the health system of Turkey, providing consultancy services to international persons and organizations concerning health systems, health financing and public-private partnership models, meeting international requests for the establishment and development of systems in these areas, and drawing up and implementing projects,
- Opening and operating health organizations, establishing partnerships and conducting cooperation abroad,
- Engaging in the supply of medicines and medical devices and supplies,
- Cooperating with the relevant institutions on policies and strategies, service delivery standards, accreditation criteria, price tariffs and legal regulations related to international health services and making recommendations to the Ministry of Health on these issues,
- Conducting activities for healthcare education, mediating the provision of foreign students for domestic educational institutions, and opening educational institutions and conducting educational activities abroad,
- Developing incentives for education in the health professions and supporting international students and educational institutions in this field, and
- Engaging in national and international congresses, seminars, and similar activities within its field of activity, conducting research, and publishing.

According to Decree Law No. 663, USHAŞ is not subject to:

- the Public Procurement Law No. 4734 of 4 January 2002, except for the provisions regarding penalties and prohibition from tenders,
- the Public Procurement Contracts Law No. 4735 of 5 January 2002, or
- the Law on Public Economic Enterprises No. 233 of 18 June 1984.

In accordance with subparagraph (e) of Article 3 of the Public Procurement Law No. 4734, USHAŞ is exempted from this Law with respect to purchases of goods and services in its field of activity, excluding the provisions on penalties and prohibition from tenders.

It is apparent from the above that USHAŞ is a state-owned enterprise with a particular status. Successful examples of diplomatic activities in trade, public health, and other fields around the World point to the importance of combining private sector dynamism and state assurance in the organizations that carry out these activities.

In this context, the status of USHAŞ has provided it with an important privilege. During the COVID-19 pandemic process, USHAŞ has been able to deploy its financing capacity, private sector dynamics, ability to take decisions rapidly and state backing to play an important role in the supply of the masks and protective materials needed by healthcare professionals and the public.

The USHAŞ response to COVID-19

At the beginning of March 2020, the Ministry of Health of the Republic of Turkey conferred on USHAŞ the task of supplying protective materials to public hospitals as part of the effort to combat the COVID-19 outbreak. This duty was bestowed upon USHAŞ in line with its legal authority – referred to above – to engage in “the supply of medicines and medical devices and supplies”. USHAŞ began to supply surgical masks on 3 March 2020, one week before the first case was detected in Turkey on 10 March 2020.

Procuring quality products

After USHAŞ was identified as sole supplier by the Ministry of Health of the Republic of Turkey, all personal protective equipment manufacturers and traders operating in Turkey were invited to sign a contract with it under which it would purchase their products at a fixed price. One box of sample products was requested from each of the manufacturers who sought to make supplier contracts with USHAŞ, together with their existing certificates. The sample products were examined in detail both by USHAŞ and by officials of the Ministry's General Directorate of Public Health. Thus:

- Three-layer masks were inspected to check whether they were ultrasonic and whether the melt-blown filter, nose wire and ear loops were stitched or ultrasonically welded. Those masks that were pre-approved were sent to Ministry of Health authorities for approval.
- In addition to the known suppliers of N95/FFP2 type masks, all N95/FFP2 masks brought to USHAŞ and pre-approved were sent to laboratories for testing, if deemed necessary, following consultations with the Ministry of Family, Labour and Social Services, which is the ministry responsible for the surveillance of products of these kinds on the market.

For all the products the samples of which were approved, the quality certificates of the suppliers were examined in detail. Those investors, textiles companies and other manufacturers whose samples were approved but who had started to supply masks and other PPE products during the pandemic without quality certificates, were directed to certification companies accredited by the European Commission to obtain quality certificates. Certification companies in Turkey were informed to enable them to obtain quality certificates rapidly. Companies also had the option of applying individually to quality certification bodies abroad accredited by the European Commission.¹²⁸ USHAŞ rapidly completed the procurement procedures for suppliers with valid documents.

No product has been purchased from any supplier without an approved sample and quality certificates. The products supplied were compared with the samples, and all non-conforming products were returned to their suppliers with appropriate warnings.

Distribution of PPE

USHAŞ created supply, distribution, and logistics networks for the required PPE, and planned and managed the procurement processes on a daily basis.

Surgical masks were distributed through three different channels: public and university hospitals, private health organizations, and institutions and organizations. In addition, masks were distributed freely to the public via pharmacies, provincial governorates and ePTTavm, the online retail arm of the Post and Telegraph Corporation (PTT).

The procurement process started by meeting the needs of public hospitals, which were prioritized at first, and later expanded to university hospitals, private hospitals, public institutions and organizations, industrial organizations and finally to the public as a procurement for free-distribution.

In order to determine the daily PPE requirements of private health institutions, USHAŞ cooperated with the Private Hospitals and Health Institutions Association (OHSAD), taking into account the numbers of beds and intensive care beds in all the private hospitals, private dialysis centres and other private health institutions across Turkey.

In this context, an ordering module was launched on the USHAŞ website. Private health institutions entered their requirements on this module with a username and password, and USHAŞ supplied the equipment at purchase cost without adding any profit margin. Under a cargo agreement between USHAŞ and the PTT, the PPE was delivered to private health institutions free of charge.

In order to provide citizens with free masks, USHAŞ distributed about 150 million masks to the major pharmaceutical warehouses in Turkey in cooperation with the Turkish Medicines and Medical Devices Agency (TITCK). USHAŞ distributed masks to all provincial governorates to meet the needs of the industrial establishments in the provinces concerned.

Key achievements

During an extraordinary period when the demand was very high compared to the supply, USHAŞ succeeded in increasing the daily supply of PPE and reducing the prices, making use of its authority as single buyer and distributor. The numbers of masks available increased to the extent that it became possible to distribute them to the public free of charge, thanks to meetings with sector associations and representatives.

In total, USHAŞ has delivered and distributed the following items, primarily to public hospitals affiliated to the Ministry of Health, university hospitals and private hospitals:

- 361,095,980 three-layer surgical masks
- 13,424,668 FFP2/N95 masks
- 6,848,068 protective overalls
- 1,950,855 pairs of protective glasses
- 1,121,577 aprons
- 104,613,047 examination gloves.

USHAŞ has also played an important role in the supply of Favipiravir, which is a vital drug in the treatment of COVID-19, and has supported the production and distribution of COVID-19 diagnostic kits and domestic ventilator devices (see below).

Major challenges encountered and solutions found

At the time when USHAŞ launched the procurement process, the prices of protective materials had increased markedly by comparison with the pre-pandemic period. The public and private sector had begun to have trouble obtaining masks and protective equipment. Hospitals and healthcare workers were facing difficulties in accessing the masks and other protective equipment they needed.

One of the main reasons for the price increase was that manufacturers were not offering their goods on the domestic market but had turned towards export markets. In addition, the existing machinery parks and daily production capacities of the registered manufacturers were insufficient to meet the current domestic market demand from public and private hospitals, public institutions, industrial organizations, and the public.

Meanwhile, due to the increasing demand, raw material costs had increased four- or five-fold compared to the pre-crisis period.

These challenges were solved as follows:

1. First of all, in order to shift production from exports to the domestic market, exports of masks and protective equipment were made subject to preliminary permits, thus increasing the supply in the domestic market:
 - a. As part of the measures to fight COVID-19, the import and export of certain products are subject to the approval of the Turkish Pharmaceuticals and Medical Devices Authority (TITCK). The aim of this measure is to ensure access to safe products, manage the supply of products that are critical for the treatment of COVID-19, ensure the smooth functioning of the health services and protect public health. Companies must obtain TITCK approval in order to export PPE and products subject to the Regulation on Medical Devices. This includes medical and surgical masks, sterile medical gloves, intubation tubes and intensive care monitors. Approval must also be obtained for the import of certain medical diagnosis kits. Approval applications are made via the electronic application system tr. EBS.
2. High market prices were brought under control by providing manufacturers of masks and other protective materials entering into contracts with USHAŞ with purchase guarantees:
 - a. The purchase guarantee made it possible for manufacturers and investors to purchase machinery and increase their daily output. Contracts were signed with 300 different companies for the supply of masks and protective equipment.
 - b. Thanks to the purchase guarantee provided by USHAŞ, the masks were procured at more reasonable prices. The price of a mask fell from TRY3.00 to TRY0.80 and the price of an N95 mask was reduced from TRY6.00 to TRY9.50.
3. Production contracts were signed with major garment manufacturers in return for a supply of the fabric required for the production of PPE. In this way, alternative productive resources were put to use while employment was created for the clothing industry, which was suffering due to the epidemic.
4. USHAŞ entered into cooperation with the Southeastern Anatolia Exporters Union, an NGO representing domestic manufacturers of the fabrics required for PPE. As a result, the PPE manufacturers who signed contracts with USHAŞ were able to obtain the fabrics they needed and the prices of fabric retreated to a level close to that of the pre-crisis period.

As a result of these activities, the supply of surgical masks, which was 1 million per day at the beginning of the pandemic, reached 25 million per day as of 20 April 2020.

Development of COVID-19 Diagnostic Kits and Ventilators

In addition to personal protective equipment, USHAŞ provided – and still provides – financial support and purchase guarantees to start-up firms supplying the ventilators and PCR kits that have become so essential during the pandemic. Ventilators had been in particularly short supply, and their prices had risen by a factor of four or five. Following USHAŞ's initiative, public hospitals were able to obtain ventilators at more reasonable prices.

Meanwhile, USHAŞ played very critical roles in financing and commercializing the production of national, locally produced COVID-19 diagnostic kits and respiratory devices:

Biospeedy COVID-19 diagnostic kits:

In order to reduce the cost of COVID-19 diagnostic kits in Turkey and to increase testing capacity to the required level, researchers from the Microbiology Reference Laboratories and Biological Products Department of the General Directorate of Public Health at the Ministry of Health and from Bioeksen ARGE Technologies Ltd, jointly developed the BioSpeedy COVID-19 Diagnostic and Rapid Viral Nucleic Acid Isolation Kit. This kit is based on the reference protocol published by WHO on 17 January 2020 for molecular testing of SARS-CoV-2 using the 'diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR' method.

USHAŞ provided a purchase guarantee as well as financing for the production of the test kits. In this way, Turkey developed a domestic diagnostic test for COVID-19 using its own means. Hence:

1. A new product has gone through the phases of research and development (R&D) and product development (P&D) and been commercialized, enabling a start-up technology company to grow and make new investments.
2. So far, USHAŞ has delivered approximately four million test kits to the Ministry of Health at affordable prices, thus making a significant contribution to the Ministry's fight against COVID-19 and the state budget.
3. Thanks to the state backing and endorsement that USHAŞ enjoys, approximately two million kits have been exported, making use of inter-state commercial opportunities, and the export revenues have generated funds for new investments.

The rights to produce and commercialize the said test, which gives results with 97% accuracy in less than 90 minutes, are the sole property of USHAŞ. The product has been approved by FDA, USA as of September 2020. WHO approval for the aforementioned product has been received in November 2020.

Domestic mechanical ventilator device (Biyivent):

The Biyovent Intensive Care Type Mechanical Ventilator was developed by Biosys Biyomedikal Mühendislik San ve Tic Ltd Şti (Biosys). With the onset of the COVID-19 pandemic in Turkey, the Ministry of Health and the Ministry of Industry and Technology launched an initiative to ensure the mass production of the product. Under this initiative, the intellectual and industrial property rights and production and commercialization rights for this product have been transferred to USHAŞ for a period of ten years.

Biyivent has made history as Turkey's first national, domestically produced respiratory device. As with the domestic diagnostic kit, the transfer of the industrial property rights, the provision of investment financing by USHAŞ and the purchase guarantee model have had three important results:

1. A new product has gone through the phases of research and development (R&D) and product development (P&D) and been commercialized, enabling a start-up technology company to grow and make new investments.
2. Respirators have been supplied to Ministry of Health hospitals at cost price and the budgets of the ministry and the state have benefited.
3. Thanks to the state backing and endorsement that USHAŞ enjoys, approximately 4,000 ventilators have been exported, making use of inter-state commercial opportunities, and the export revenues have generated funds for new investments.

The device has a CE certificate and has reached the final stage of the US FDA approval process. Its design and features have earned it the acceptance and appreciation of healthcare professionals.

Biyivent has also attracted significant demand in the domestic market and from many other countries. The number of devices ordered so far is 7,844, of which 6,541 have been delivered.

The development and export of ventilators produced entirely through domestic and national means at such a crucial period constitutes one more reflection of Turkey's successful struggle against the COVID-19 pandemic. At the same time, the wide international recognition of the device has made an important contribution to the promotion of the country's health system and health technology exports.

Coordination of equipment grants to other countries

In coordination with the Ministry of Health, USHAŞ has donated medical supplies to 20 countries and two autonomous republics on behalf of the Republic of Turkey during the COVID-19 period, to assist them in tackling the pandemic.

Medical supplies have been sent to Iran, Moldova, Palestine, Somalia, the United Kingdom, Montenegro, Kosovo, Bosnia and Herzegovina, Serbia, North Macedonia, Tunisia, Namibia, Guinea, Paraguay, Chad, Afghanistan, Uzbekistan and Pakistan under the grant agreements reached so far. In addition, medical supplies have been sent to the USA, China, Dagestan (Russia) and Sandzak (Serbia) without formal grant agreements.

The medical supplies despatched include a wide range of equipment, among them COVID-19 diagnostic kits, surgical masks, N95 masks, coveralls, aprons, and Turkey's first national, domestically produced ventilators. Approximately three million items have been donated in total.

Exports

In addition to all the above activities for the protection of public health, USHAŞ has exported millions of items to a total of over 30 countries and international organizations such as UNICEF and WHO. These include:

- medical devices
- 14,224,900 items of PPE
- 1,025,802 items of medical consumables
- 2,050,000 diagnostic test kits.

The experience of USHAŞ during the COVID-19 pandemic has been acknowledged as an example for the Supply Chain Group within the Health Coordination Committee of the Turkic Council.

Central purchases of high-quality PPE from USHAŞ by the Ministry of Health of the Republic of Turkey, the Republic of Moldova and the Republic of Kyrgyzstan have been funded by the World Bank under a protocol with the institutions concerned.

Conclusion

USHAŞ's role as a supplier of personal protective equipment (PPE) for combating COVID-19, the success of its rapid supply and distribution network, its contribution to raising production and reducing prices, and the support it has provided for the financing, production and export of domestic ventilators and diagnostic kits constitute an important success story.

The initiatives taken by USHAŞ to meet urgent needs under pandemic conditions have become models for others to follow. This has been possible due to the dynamic structure of USHAŞ, its rapid decision-making processes, its legal capacity to provide a purchase guarantee on behalf of the state, its status as a company able to partner and/or invest, and the financing opportunities which it has offered in commercial purchases. In this sense, the crisis has been turned into an opportunity.

Annexes:
Annex I: List of Non-woven Fabric Manufacturers in the World¹²⁹

NO.	COMPANY NAME	COUNTRY	LOCATION	CONTACT NO.	E-MAIL
1	Ahlstrom-Munksjö	Germany	Dettingen	49 7123 977 0	info.dettingen@ahlstrom-munksjo.com
2	Argent International, Inc.	USA	Plymouth, MI		
3	Asahi Kasei	Japan	Tokyo		
4	Avanti	USA	Cranbury, NJ		
5	Avgol Non-wovens	USA	Nc		
6	Berry Global	USA	Evansville	(812) 424-2904	
7	ConForm Automotive	USA	Bingham Farms, MI		
8	Daiwabo Polytec	Japan	Osaka	81-6-6281-2512	
9	Dalian Riuguang	China	Dalian	0086-411-62695838	
10	Draper Knitting Co., Inc.	USA	Canton, MA		
11	DuPont	USA	Ohio	(740) 474-0111	
12	Fibretek Personal Care	USA	NC	13367991323	msa@fibretekpersonalcare.com
13	First Quality Non-wovens	USA	NC		
14	Fitesa	USA		+1 864 967 5600	
15	Freudenberg	Germany	Weinheim	+49 6201 80 6264	
16	Georgia Pacific				
17	Glatfelter	USA	North Carolina	1-866-744-7380	
18	Halyard Health	North America		1-844-425-9273	
19	Hollingsworth & Vose	USA	East Walpole	15.088.502.000	
20	IFSCO Industries, Inc	USA	Chicago, IL		
21	Jacob Holm	USA			info@jacob-holm.com
22	Jofo Non-wovens	China	Guangzhou	0086 (20)38770816	jofogroup@jofo.com.cn
23	Johns Manville	USA		1-303-978-2000	
24	Kimberly-Clark	USA		1-888-525-8388	
25	KNH Enterprise	Taiwan	Taipei		
26	Kuraray	Japan	Tokyo		
27	Low & Bonar	United Kingdom	London	020 7535 3180	
28	Lydall Inc	United Kingdom	Manchester	860.646.1233	info@lydall.com
29	Marves Industries	USA	Hildebran, NC		
30	MBK Tape Solutions	USA	Chatsworth, CA		

NO.	COMPANY NAME	COUNTRY	LOCATION	CONTACT NO.	E-MAIL
31	Midwest Filtration Company	USA	Cincinnati, OH		
32	Mitsu Chemicals	Japan	Tokyo		
33	MWT Materials, Inc.	USA	Passaic, NJ		
34	Nan Liu Enterprise	China	Zhejiang	86-573-85136616	
35	PFNon-wovens	Czech		+420 515 262 411	info@pfnnonwovens.cz
36	Precision Custom Coating	USA	Totowa	(973) 890-3873	info@precisiontextiles-usa.com
37	Propex Inc	USA	Chattanooga	800-621-1273	800-621-1273
38	Sandler Group	USA	California	8.583.446.160	
39	Saudi German	Saudi Arabia	Bahreyn	966 (013) 8122111	info@sgn.com.sa
40	Shalag Non-wovens	Israel	Kibbutz Shamir	972-4-694-7856	sales@shalag.co.il
41	Suominen Corporation	Finland	Helsinki	358 10 214 300	communications@suominencorp.com
42	Tenowo	Germany	Deutschland	+1 704 732 3525	
43	Toray Advanced Materials	Korea			
44	Toyobo	Japan	Tokyo	077-571-0083	tc-cae@hotoyobo.co.jp
45	TWE Group	Germany	Deutschland	49 2572 205 0	info@twe-group.com
46	Union Industries	United Kingdom	West Yorkshire	44 (0)113 244 8393	enquiries@unionindustries.co.uk
47	Unitika	Japan	Osaka	81-6-6281-5533	
48	Xamax Industries, Inc.	USA	Seymour, CT		
49	Zhejiang Kingsafe Group	China	Zhejiang		

Annex 2: List of Non-woven Manufacturers in Turkey¹³⁰

NO.	COMPANY NAME	PROVINCE	CONTACT NO.	E-MAIL
1	3TEKS Tekstil	Gaziantep	+342 337 24 16	
2	Akinal Sentetik Tekstil	Gaziantep	+342 337 20 60	as@asnonwovens.com.tr
3	Almina Non-wovens	İstanbul	+212 671 2760	
4	Apex Non-wovens	Adana	+322 394 44 70	info@apexnonwovens.com
5	Aras Tekstil	İstanbul	+212 502 26 71 - 72	info@arastekstil.com.tr
6	Baknoteks	Kayseri	+352 321 14 14	info@baknoteks.com
7	Başat Laminasyon	İstanbul	+212 537 24 15	info@basatlaminyasyon.com
8	Bayteks Teknik Tekstil	Kilis	+348 822 10 60	info@bayteks.com
9	Berfa Grup	Kayseri	+0352 224 74 57	
10	Bezci Tekstil	Tekirdağ		bezcitekstil@bezcitekstil.com

NO.	COMPANY NAME	PROVINCE	CONTACT NO.	E-MAIL
11	Broche Medikal	İstanbul	+212 438 02 42	info@brochemedikal.com
12	Cordeks Non-woven	Gaziantep	+342 337 24 35	cordeks@cordeks.com
13	Eruslu Non-woven	Gaziantep	+342 357 07 20	nfo@engnonwovens.com
14	Felix Non-wovens Films and Laminates	Eskişehir	+222 236 23 63	info@felixnonwovens.com
15	Fibreteks	Tekirdağ	+282 725 40 08-09	salestr@fibreteks.com
16	Flokser A.Ş	İstanbul	+532 461 67 41	levant.ilhan@flokser.com.tr
17	General Non-wovens & Composites	Gaziantep	+342 337 40 41	info@generalnonwovens.com
18	Gülsan Non-woven	Gaziantep	+342 337 11 80	info@gulsanholding.com
19	Hassan Tekstil	İstanbul	+212 886 53 30	info@hassan.com.tr
20	Hüner Nano Tekstil	Gaziantep	+342 337 25 35	info@hunernano.com.tr
21	Kara Holding	Gaziantep	+342 337 14 88	info@karaholding.com
22	Kimsan Non-woven	Kayseri	+352 504 09 00	info@kimsantextile.com
23	Kurt Non-woven	Gaziantep	+342 337 4570	kurt@kurtnonwoven.com
24	Labor Tekstil			
25	Lotus Tekstil	İstanbul	+212 734 37 75	info@lotustekstil.com.tr
26	MHK Medikal Tekstil	Gaziantep	+342 341 93 66	info@mhkmedikal.com.tr
27	MicronTeknik Tekstil	Bursa	+224 249 50 51	info@microteknik.com
28	Milkay Non-woven	Kayseri	+352 321 17 51	info@milkay.com.tr
29	Mogul Tekstil			
30	Napal Non-woven	İstanbul	+212 736 05 55	info@merkastekstil.com
31	Ribond Tekstil	Gaziantep	+342 329 50 00	ritas@ritas.com.tr
32	Salteks Tekstil	İstanbul	+212 789 27 90	
33	Simco Tekstil	Denizli	+258 372 09 75	
34	Şahkan Non-wovens	Gaziantep	+342 321 87 18	muhasabe@sahkannonwovens.com
35	Teknomert	Kahramanmaraş	+344 257 91 19	info@teknomert.com
36	Teymur Tekstil	Gaziantep	+342 337 46 46	info@teymurteknik.com
37	Tezman Holding	İstanbul	+212 253 62 40	info@tezmanholding.com
38	Vateks Medikal	İstanbul	+212 253 62 35	info@vateks.com
39	Yeni Mert Tekstil	Adana	+322 352 83 75	yenimert@hotmail.com
40	Yıldırım Tekstil	İstanbul	+212 886 62 72	bilgi@yildirimteknik.com.tr

Annex 3: List of Mask Machine Manufacturers in Turkey³¹

NO.	COMPANY NAME	PROVINCE	CONTACT NO.	E-MAIL	WEB
1	Astaş Endüstri	İstanbul	+212 630 89 00	astasjuki@astasjuki.com	www.astasjuki.com
2	Çağrı Makine	İstanbul	+212 798 28 86	info@cagrimakina.com	www.cagrimakina.com
3	Ant Ambalaj	İstanbul	+532 701 02 08	info@antambalaj.com	www.antambalaj.com
4	Aysar Grup Makine	İstanbul	+216 466 00 86	info@aysargrup.com.tr	www.aysargrup.com.tr
5	Baysonic Ultrasonik Teknolojileri	İstanbul	+212 879 17 01	baysonic@baysonic.com	www.baysonic.com
6	Bizmak Makine	İzmir	+232 375 33 35	info@bizmakmakina.com	www.bizmakmakina.com
7	Cedit Makine	Bursa	+224 360 30 40	info@cedit.com.tr	www.cedit.com.tr
8	Çoşkunlar Mekatronik	İstanbul	+543 869 482 6	info@coskunlarmekatronik.com	www.coskunlarmekatronik.com
9	Demas Makine	Bursa	+224 341 71 00	demas@demas.com.tr	www.demas.com.tr
10	Demirbilek Makine	İstanbul	+212 511 23 81	info@demirbilektd.com.tr	www.demirbilektd.com.tr
11	Diferro Calenders	İstanbul	+212 608 08 08	info@diferro.com.tr	www.diferro.com.tr
12	DM Makine Otomasyon	İstanbul	+553 728 52 70	dmmakina.otomasyon@hotmail.com	www.dmmakinaotomasyon.com
13	Has Makine	İstanbul	+212 279 77 50	info@hasmakina.com.tr	www.hasmakina.com.tr
14	İnci Makine	Bursa	+224 341 55 54	info@incimakina.com.tr	www.incimakina.com.tr
15	JET Otomasyon	İstanbul	+212 671 12 44	info@jetotomasyon.com	www.jetotomasyon.com
16	Ledmaksan Makine	İstanbul	+212 472 08 49	info@ledmak.com	www.ledmak.com
17	Mahir Plastik	Kocaeli	+262 646 73 43	info@mahirplastik.com.tr	www.mahirplastik.com.tr
18	Meser Wermac	İstanbul	+212 699 00 00	info@wermac.com.tr	www.wermac.com.tr
19	Mispa Makine	İstanbul	+212 549 52 65	info@mispamakina.com.tr	www.mispamakina.com
20	Noya Mekatronik	İzmir	+232 375 65 71	info@noyamak.com	www.noyamak.com
21	Örnek Makine	Gaziantep	+342 337 86 01	info@ornekmakine.com	www.ornekmakine.com
22	Özbiilim Makine	İstanbul	+212 855 42 43	info@ozbiilim.com	www.ozbiilim.com
23	Pivottex Makine	Denizli	+258 251 77 76	info@pivottex.com	www.pivottex.com
24	Pro-ser Makine	İstanbul	+212 671 02 58	info@pro-ser.com	www.pro-ser.com
25	Robotech Makine	İstanbul	+212 472 01 01		www.robotech.com.tr
26	Sarem Makine	İstanbul	+444 97 76	sales@sarem.com.tr	www.sarem.com.tr
27	Sonicsan Ultrasonik Sistemler	İstanbul	+533 353 4714	info@sonicsan.com	www.sonicsan.com
28	Sonik Makina	İstanbul	+212 281 24 39	info@sonikmakina.com	www.sonikmakina.com
29	Sonimak Makine	İstanbul	+216 415 52 00	info@sonimak.com	www.sonimak.com
30	Uygur Makine	İstanbul	+537 610 43 42	uygursalih@gmail.com	www.uygurmakina.com
31	Uygurlar Makine	Kırşehir	+386 272 11 11	info@uygurlarmakina.com.tr	www.uygurlarmakina.com
32	Vahdet Makine	İstanbul	+212 657 21 15	info@vahdetteknikmakina.com	www.vahdetteknikmakina.com

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**United Nations Development Programme**

Istanbul International Center for Private Sector in Development
Key Plaza, Abide-i Hürriyet Cad. İstiklal Sok. No:11 Floor: 5
Şişli, 34381 Istanbul, Turkey

For more information: www.undp.org | www.iicpsd.org

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