

## FAQs for PPE Production

1. What are the cleanroom requirements and sterilization requirements for PPEs?

Typically, clean room is required in surgical environments. If your customers are patients that could be exposed to bacteria or viruses or under surgery, then you want sterile equipment for your products. Additionally, there are regulations in this regard. There are standards that need to be maintained, and the company should pay attention to local requirements. For example, in Bangladesh level 3 and level 4 of PPE production has sterilization requirement.

Anytime when something needs to be sterile is when clean rooms or at least some post-production sterilization process comes into play.

2. How can companies get certificated with their products with the requirements that are still in place today?

For starters, it is important that for each country the company reviews the local regulations and then of course which markets the PPE products are meant for. In very simple terms for civil use, there are typically, fewer or certainly no medical standards.

For anything that's destined for medical use or healthcare use, there will typically be standards, there are guidelines from WHO. The disease commodity package includes mainly the PPE items that are intended for use by medical professionals. WHO does not have specifications for civilian masks and there is no clear recommendation for the usage of cloth masks to use in community settings. The recommendations are geared towards protection against infection mainly in the healthcare setting.

Additionally, if the company wants to get FDA approvals and if they do not claim to provide viral protection, but they put certain labeling and disclaimers on the products, those products can also be used in medical settings. It is important above all that the company properly labels all products and it is recommended that the company has some expertise and expert advice depending on the distribution of the product.

3. Are there any alternative fabrics other than nonwovens that can be used for making the gowns?

Alternative fabrics are Wetlaid for gown manufacturing, but it must meet the standards. There have been reports of Wetlaid material that does not pass the viral barrier standards. There is also Spunbond or Spunbond Meltblown Spunbond (SMS), but this should also be procured cautiously as there are low weight material coming from China that does not protect the wearer or protect the patient.

These substitutes that are available in the market are not of the greatest quality, and unfortunately a plastic bag would do a better job than buying anything on the market currently.

4. Where can a company source the nonwoven special materials from? Does Ahlstrom-Munksjö have the capacity to supply these materials?

Ahlstrom-Munksjö has several assets producing those materials. Our SMS comes from Mundra in India in the Gujarat State. We laminate those materials in Connecticut, USA, and we're looking at investments to further add lamination capacity, as both assets are well within their capacity. We would encourage that you channel your request through our head of sales in Asia so that we can look at volumes, which customer you work with so that we can then answer adequately to your request. But again, a word of caution here we've gone to extreme level of demands and we need to prioritize existing customers and it's looking at rather large contract now and we have a large commitment to cater to our existing customers.

Additionally, what we are also doing in this global fight against COVID-19 pandemic is that we are trying to convert our filtration. We are the world's leading producer of filtration material for transportation and industrial purposes and we are trying to convert and redirect those capacities into materials that can be used in, for instance, face masks. So, we have several assets in Europe Asia as well as North America. However, it is clear that for civil face mask type of protection, there is much more material available than for the highest quality standard materials. Face masks requirements are quite high, but we are also actively expanding our capacities.

5. How fast can a company convert a part of shirt manufacturing facility into PPE mask and gown manufacturing facility?

Typically, the span is about one week, but that's largely determined on the materials that a company have access to. Then there's also the hardware that they're using, for instance for a shirt manufacturer, the company is probably using multi ply cutter that can very easily be changed over to PPE production with some changes in consumables that Ahlstrom-Munksjö can set the company up with.

However, there's some manufacturers that would have a more difficult conversion. That still typically takes a matter of days. A manufacturer can transform on their own, but that takes a lot longer. It's usually faster – a matter of days – if Ahlstrom-Munksjö works with the manufacturer directly.

6. Proper PPE requires lots of standards and lab tests and most of the cases require accredited lab facilities. How fast can companies get these facilities locally and what can be done without having this readily available?

In Bangladesh the local garments laboratories do not have the proper apparatuses for the required test. So, in response to this, Bangladesh has been maintaining the WHO specification as the minimum standards. The raw materials come with its own set of certifications; thus, third-party testing could be reduced. If the company is doing their due diligence on the actual fabric coming in, testing for the product according to the local capacity, then it is assumed that there is a reasonable quality assurance to deal with this emergency situation.

Another step is having the involvement of BUET in parallel to the regulatory authority. BUET is working on establishing experimental models to conduct some of the tests where the full-scale accredited apparatuses and tests are not available. It is optimistic that the companies will be able to conduct these tests on non-accredited processes at the university laboratory and perhaps some of the other local laboratories that have been approved by the regulatory authority for the future.

7. Are there any specific facilities regarding capital expenditure financing and more so in working capital financing? How to get financing or for foreign assistance and how fast can it be?

In response to COVID-19, World Bank Group has come up with a \$14 billion fast-track facility, of which IFC has \$8 billion, of which \$2 billion has been dedicated to the existing clients. What clients can do for this fund is identify the use of proceeds, come up with business cases and present them to IFC for further processing in terms of regular funding and if there is any short-term liquidity funding required. This fund is only available to existing IFC clients as IFC wanted to act quickly to help our existing portfolio in this space and this is phase one of our response. We are always open for business cases for new clients as a phase two is hopefully coming up soon, which will consider new clients. Anything else that comes along for a standard financing application can be considered for further processing.

8. Our products have been tested by SGS Bangladesh and are now okay to export to Europe, do we possibly need CE Certificate? If so, how can we obtain that?

If referred to face mask, and if especially these products go into medical purposes, or sold to public or in tandem to contract with the government then yes, then company would need to take the certification.

The best way to get a fast certification is to get in touch with recognized labs in Europe as only recognized labs can give the correct level of information. The process of CE certification is quite long, and the best way to do this is by using Ahlstrom-Munksjö's channels as they can address towards assessing the correct lab to pursue in order to get this certification. If the product has been tested by select laboratories in Europe, then it is easier to sell the product in Europe.

9. We are in performance fabric business supporting our technical garment (skiwear, mountaineering jackets etc.) manufacturing. If we make gowns out of PU coated polyester taffeta, would we need to sterilize those?

Yes. Typically, will PPE will go through an ETO sterilization and before being delivered to the hospitals. There are some very specific requirements that needs to be fulfilled when it comes to viral protection as well as breathability and other properties. It is doubtful whether this can be turned into a certified PPE protection material.

10. What is the fabric requirement for the fabrics for a civilian or a consumer mask? Especially with knitted fabric.

What is important is that companies don't put materials that are not protected at all in the market. Many non-woven kind of materials are not tested correctly as people tend to use whatever they have to do to produce this mask, and then people get infected anyway.

Droplets have a certain level of face velocity and these droplets are normally poly dispersed aerosol. There needs to be a minimum efficiency level requirement which is measured by efficiency of droplets of 1 micron and 3 microns in this case. For 3 microns, a 100% efficiency of droplets is required and for the 1 micron, an efficiency of 80-85% is required. These efficiencies are tested by **TSI**.

11. Is Gerber Sri Lanka team aligned with the PPE support program?

Yes. For Sri Lanka, it is part of the Southwest Asia team. The team is aligned for PPE technical support. We have a China partner there who we work with. Alternatively, the Gerber team can also support all your technical requirements PPE in Bangladesh, Sri, Lanka and India. For other further regions, we also have other teams for example for Vietnam or Taiwan and other places. We have different entities around the world and the task force for PPE is a global program.

12. Can you please tell us which level of standard we are if we have?

The upcoming DGDA circulars will make this clearer for which levels are accepted by the DGDA. The WHO team can pass specific questions to the technical working group if with more details.

13. How long do you predict that this high demand for surgical mask and PPE will last?

This situation can be looked at different phases. The recovery phase and the life post COVID-19. We do not know how long these phases will be but what we know is that the vaccines will take a

while. So, until we get to a post COVID-19 phase, there will be a long-term reality with the virus and at least with the PPE. There are also estimates that there might be stockpiling happening in the post COVID-19 phase.

This new normal has brought in a heightened sense of the need for protection and especially personal protection against pathogens. This applies equally for the health sector, first responders and for the general public as well. It is very difficult to tell how long this will last but even when the disease plateaus and starts to hopefully curve downwards, there will still be this new reality that we will be dealing with and the new preparedness that has been installed in health workers and other first line workers, and that will last for a while.

The demand is going to be there for a few months, but ultimately it is highly recommended that a company assesses how the infections will affect their own country and how their operations will affect this. Ultimately, there should be a risk assessment done from the business, advise should be taken from experts who understand the market dynamics, and a firm business decision should be made.

14. A recent study is that t-shirt need fabric manufacturing fabric is highly efficient for manufacturing face masks. It is sometimes equal to surgical mask. Is this recognized by WHO?

So far, WHO is not recommending this.