

# Production of PPE

Points to consider when launching production of PPE

1. Demand in the market
2. Type or products including standards
3. Machinery and workshop conditions
4. Materials

## DISCLAIMER

*Attached is a selection of technical documents on personal protective equipment that IFC has collected from publicly available sources (e.g. official WHO requirements) and from companies which have started PPE production during the COVID-19 crisis. We are sharing this information with the sole purpose of giving an example of possibly relevant technical information only. IFC does not assume or accept any responsibility for the accuracy, fitness for purpose or completeness of the information provided in these documents.*

# MASKS



Respirator N95



Pleated surgical mask

<https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks>

<https://multimedia.3m.com/mws/media/13878570/health-care-brochure.pdf>

[https://www.3m.com/3M/en\\_US/company-us/all-3m-products/~/3M-Health-Care-Particulate-Respirator-and-Surgical-Mask-1860-N95-120-EA-Case/?N=5002385+3294795990&rt=rud](https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Health-Care-Particulate-Respirator-and-Surgical-Mask-1860-N95-120-EA-Case/?N=5002385+3294795990&rt=rud)

<http://multimedia.3m.com/mws/media/3127030/masks-and-respirators-tri-fold-brochure-eng.pdf>

<https://www.ukmeds.co.uk/blog/what-s-the-difference-between-ffp1-ffp2-and-ffp3-face-masks>

Particulate respirator, grade N95 or higher.	N95 or FFP2 respirator, or higher Good breathability with a design that does not collapse against the mouth (e.g. duckbill, cup-shaped).	<ul style="list-style-type: none"> <li>• Minimum "N95" respirator according to FDA Class II, under 21 CFR 878.4040, and CDC NIOSH, or</li> <li>• Minimum "FFP2 according to EN 149, EU PPE</li> <li>• Regulation 2016/425 Category III, or equivalent</li> </ul>
Mask, surgical – health care worker.	Surgical mask, good breathability; internal and external faces should be clearly identified Type II or higher.	<ul style="list-style-type: none"> <li>• EU MDD Directive 93/42/EEC Category III or equivalent</li> <li>• EN 14683 Type II, IR, III R</li> <li>• ASTM F2100 minimum level 1 or equivalent</li> </ul>
Mask, surgical – patient	Surgical mask, good breathability; internal and external faces should be clearly identified Type I.	<ul style="list-style-type: none"> <li>• EN 14683 any type including Type I</li> <li>• ASTM F2100 minimum level 1 or equivalent</li> </ul>

# SCRUBS, APRONS, GOWNS, CAPS, etc.



- Scrubs
- Coveralls
- Medical Gowns
- Surgical Gowns
- Non-Surgical Gowns
- Aprons

<http://multimedia.3m.com/mws/media/3431690/3mtm-surgical-disposable-gowns.pdf>

<https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns>

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	<p>Straight apron with bib,          Fabric: 100% polyester with PVC coating, or 100% PVC, or 100% rubber, or other fluid-resistant coated material.          Waterproof, sewn strap for neck and back fastening          Minimum weight: 300 g/m<sup>2</sup>          Covering size: 7090 cm (width) x 120–150 cm (height)          Reusable (provided appropriate arrangements for decontamination are in place)</p>	<ul style="list-style-type: none"> <li>• EN ISO 13688</li> <li>• EN 14126-B and partial protection (EN 13034 or EN 14605)</li> <li>• EN 343 for water and breathability or equivalent</li> </ul>
Gown	Single-use, length mid-calf.	<ul style="list-style-type: none"> <li>• EU PPE Regulation 2016/425 and EU MDD Directive 93/42/EEC</li> <li>• FDA Class I or II medical device, or equivalent</li> <li>• EN 13795 any performance level, or</li> <li>• AAMI PB70 all levels acceptable, or equivalent</li> </ul>

# MACHINERY



Cup forming machine  
Finishing machines

[https://www.youtube.com/watch?v=wN2\\_s-mguxM](https://www.youtube.com/watch?v=wN2_s-mguxM)  
<https://www.youtube.com/watch?v=kWNHwXOVio>  
<https://www.youtube.com/watch?v=ewoZ3D3IF64>



Automatic line with ultrasonic welding  
Manual ultrasonic welding machines

[https://www.youtube.com/watch?v=wivuYS\\_PZIo](https://www.youtube.com/watch?v=wivuYS_PZIo)  
<https://www.youtube.com/watch?v=a9m5qM54vCk>  
<https://www.youtube.com/watch?v=OZfHysnxSiM>



Automatic line with ultrasonic welding  
Manual ultrasonic welding machines

<https://www.youtube.com/watch?v=4B1DwMWSt8Y>  
[https://www.youtube.com/watch?v=bV\\_ZOJZkRWs](https://www.youtube.com/watch?v=bV_ZOJZkRWs)  
<https://www.youtube.com/watch?v=4RqdtSszQA>

Production with conventional sewing machinery:

- Limited range of medical textile products only.
- Product to be constructed so that needle holes do not leak.
- To avoid leakage use of seam sergers, lap seamers, seam taping should be used.

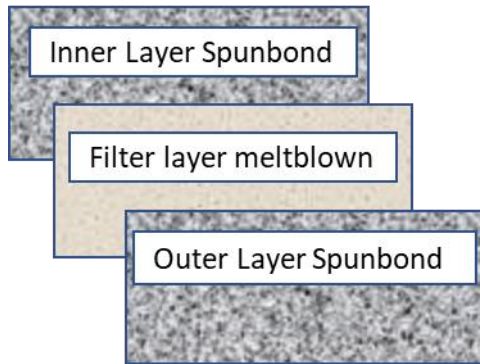
Considerations:

- Standards, certificates, testing
- Dust free workshop
- Clean room conditions
- Product sterilization

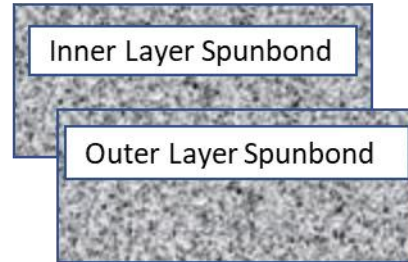
# MATERIALS



## 3 LAYER



## 2 LAYER

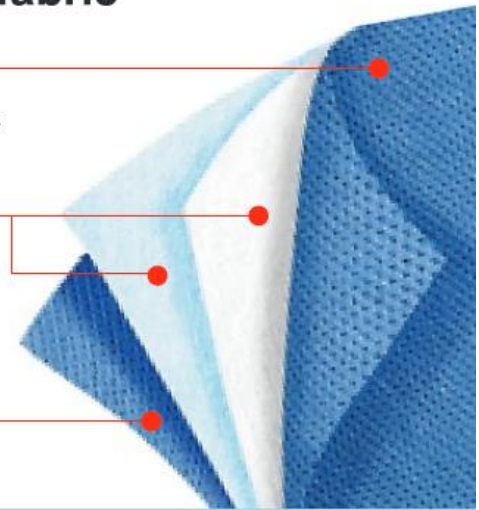


## SMMS non-woven fabric

**Outer layer** — Spunbond, repellent fabric

**2 Middle layers** — Meltblown, fluid control, bacterial barrier

**Inner layer** — Spunbond, strength



### Non-woven polypropylene fabrics

- Disposable and single use
- Outer layer for protection against liquid splashes
- Middle layer is a filter barrier to stop virus
- Soft inner layer absorbs moisture released by the wearer

### Non-woven polypropylene fabrics

- Disposable and single use
- Single layer or multilayer construction depending on use
- Middle layer(s) are melt blown non-woven fabric for filtering



# RISK LEVELS AND PRODUCTION DURING SHORTAGE OF MATERIALS

WHO 6 April 2020: [https://apps.who.int/iris/bitstream/handle/10665/331695/WHO-2019-nCov-IPC\\_PPE\\_use-2020.3-eng.pdf](https://apps.who.int/iris/bitstream/handle/10665/331695/WHO-2019-nCov-IPC_PPE_use-2020.3-eng.pdf)

	Low-Risk Personnel	Medium-Risk Personnel	High Risk Critical Personnel
<b>Personnel</b>	Medical Assistance Staff / technicians/ Administrator	<p>Doctor/Nurses/Medical Staff / Workers/ Cleaners not in direct contact with COVID-19 patients</p> <p>OR</p> <p>Healthcare workers providing treatment to COVID-19 patients not generating aerosols (cough, intubation, sample collection, vomiting, etc.)</p> <p>OR</p> <p>OPD Consultation Rooms</p>	For Use by doctors and health professional directly treating COVID-19 patients generating aerosols (cough, intubation, sample collection, vomiting, etc.) or collecting samples
<b>Key items in a PPE Kit</b>	<p>Generally no PPE Required: Table 1, pg 4</p> <ol style="list-style-type: none"> <li>1. Shoe Cover (optional)</li> <li>2. Surgical Gloves</li> <li>3. Coverall or Gown (autoclavable cotton gowns are acceptable)</li> <li>4. 3 Ply Mask (Medical Mask)</li> <li>5. Eye Goggle (not recommended by WHO)</li> </ol>	<ol style="list-style-type: none"> <li>1. Shoe Cover (optional)</li> <li>2. Surgical Gloves</li> <li>3. Coverall or Gown (autoclavable cotton gowns are acceptable)</li> <li>4. 3 Ply Mask (Ideally N95 masks)</li> <li>5. Eye Goggle or face shield (in case working in COVID wards)</li> <li>6. Face Mask (FFP2/N95)</li> </ol>	<ol style="list-style-type: none"> <li>1. Shoe Cover (optional)</li> <li>2. Surgical Gloves</li> <li>3. Coverall (ideal) or Gown</li> <li>4. Eye Goggle</li> <li>5. Face Mask (FFP2/N95)</li> <li>6. 3 Ply Mask</li> <li>7. Face Shield</li> <li>8. Apron (waterproof) if reusable cotton gowns are used</li> </ol>

Alternative Materials and Production Methods
<p>When nonwoven polypropylene materials are not available:</p> <ul style="list-style-type: none"> <li>• Gowns can be made of cotton or polyester/cotton fabric and used with aprons.</li> <li>• Woven fabrics can be used for making masks as long as a suitable middle layer for filtration is available, for example interlinings. These masks, however, should not be used by front line health care personnel.</li> <li>• Coveralls, double gloves, or head covers (hood) that cover the head and neck used in the context of filovirus disease outbreaks (e.g. Ebola virus) are not required when managing COVID-19 patients.</li> <li>• Some components, especially eye goggles, face shield, gowns (if compatible), face masks and N95 respirators may be reused after cleaning.</li> <li>• Conventional sewing machines may be used for production providing that needle holes do not create air leakage. This can be achieved through mask construction or seam taping.</li> </ul>

# SAFETY

	General Public	Low-Risk Personnel	Medium-Risk Personnel	High-Risk Personnel
<b>Mask</b>	Woven fabric mask with good filtering capability	Surgical mask Level 1-2 or Type I - II	Surgical mask Level 3 or Type III, Respirator N95 or FFP II	Respirator FFP II or N95
<b>Scrubs, Gowns</b>		Woven PE/CO for multi use or Non-woven for single use	Non-woven for single use	Non-woven for single use

## Non-woven fabrics

- Should be purchased from certified suppliers.
- Need to fulfil standard requirements, for example EN 868.

## Other fabrics

- When using alternative fabrics the final product needs to comply with standards.

## Production machinery

- Ultrasonic welding machinery for nonwovens.
- Masks produced with conventional sewing machinery need to be specially constructed to avoid air leakage through needle holes.
- Air leakage in gowns is not a problem with COVID19.

## Bacterial Filtration Efficiency (%) Requirements in Masks

SURGICAL MASK	Level 1 (US) Type I (EU)	Level 2 Type II	Level 3 Type II R
Bacterial filtration efficiency (%)	≥ 95	≥ 98	≥ 98
RESPIRATOR MASK	N95 (US) FFP1 (EU)	N99 FFP2	N100 FFP3
Bacterial filtration efficiency (%)	≥ 95	≥ 99	≥ 99.97

## Testing and Certification

- Procedure for obtaining International certificate, like CEE is time consuming, although regulations have now been relaxed.
- Testing by certified or internationally recognized laboratory: SITRA, SGS, Bureau Veritas, DRDL, BSI, Haffkine Institute, CITEV, UL, Eurofins Scientific, etc.
- Basic testing could be done locally by Universities with textile departments.