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MILANO 1863

Technical Note, version 4.1 on 07/04/2020

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General Description of typical “SURGICAL” masks

SURGICAL masks are typically made up of 3 overlapping layers of nonwoven fabric having different functions

- 1) OUTER LAYER (WORLD-SIDE):
nonwoven fabric (NWF) produced with *SPUNBOND* technology and hydrophobic coating (optional); this layer's function is to convey mechanical resistance to the face mask, and hydrophobic properties (optional).
- 2) INTERMEDIATE LAYER (FILTER LAYER):
nonwoven fabric (NWF) produced with *MELTBLOWN* technology and made of microfibre (diameter 1-3 micron); this layer functions as a filter.
- 3) INNER LAYER (FACE-SIDE):
nonwoven fabric produced with *SPUNBOND* technology; this layer has a protective function for the face, by avoiding direct contact between skin and the intermediate filter layer.

Face masks can be produced with various layers, as long as at least 3 layers meeting the above characteristics are used and functional requirements are met.

General Indications

Tests performed in our laboratories underscored the fact that to meet **particle filtration efficiency (PFE)** and **breathability** standards for face masks, the layers making up the mask must have an adequate **meltblown content** (generally in **excess of 20 g/m²**) either in a single layer, or as the sum of multiple layers.

Materials and layers for surgical masks

Tests performed on materials delivered to our laboratories confirmed that the most suitable material to produce the 3 layers of the face mask is nonwoven fabric made of either polypropylene or (as second choice) polyester.

We also observed that materials with the following characteristics were **NOT** functionally suitable and, therefore, are not deemed functionally suitable; precisely, materials:

- that are not hydrophobic/water repellent
- that lack a thick weave presenting no visible interstices even when subjected to traction
- that lack sufficient breathability
- materials made of fibre with diameter in excess of 3 micron, even nonwoven fabric (NWF).

Poor availability, in the Italian market, of nonwoven fabric (NWF) produced with *meltblown* technology (to be used for the filter layer of the face mask) has led to consider the use of **multiple layers of bonded nonwoven fabric (NWF) called SMS**, which has a small *meltblown* layer between two *spunbond* layers.

The **superimposition of 2 or more layers** of this bonded nonwoven fabric (depending on the quantity of *meltblown* present in a single SMS, which is typically in the range of 7-10 g/m²) yielded a suitable *meltblown* content to guarantee sufficient filtration capacity (>20 g/m²).

We also observed that the external layers of *spunbond* present in the bonded SMS fabric can be used as external and internal layers of face masks (see above), thus allowing **to build the layers of the mask by merely overlapping 2 or more layers of SMS**.

Materials

To date, **nonwoven fabrics** produced with *meltblown* technology and **bonded SMS type nonwoven fabrics produced and available in Italy** are, to the best of our knowledge, those listed below, among others.

Acronyms used in the table:



“M”: indicates the single layer of PP **M**-eltblown nonwoven fabric (NWF);

“S”: indicates the single layer of PP **S**-punbond nonwoven fabric;

“SMS”: indicates the combination **S**-punbond/**M**-eltblown/**S**-punbond obtained by sequential superimposition of the three single layers of *spunbond*, *meltblown* and *spunbond*.

PRODUCT	Mass per square metre (g/m ²)	Meltdown mass present (g/m ²)	MANUFACTURER
SMS	35	7	ATEX
SMS	40	8	Fitesa
SMSSMSSMS	90	10	Plastik textile (Radici group)
SMS	70	30	Ahlstrom-munksjo
Meltblown	25	25	Farè
SMS	40	7	Union Industries
TNT	30	0	Any
Meltblown T4	50	50	UFI Filters
Meltblown T6	60	60	UFI Filters
SMS-A	120	45	UFI Filters

Layers

From tests performed in our laboratories by appropriately combining the above materials, resulted that possible configurations suggested to the packers are the following. The performances obtained for the masks, in terms of filtering capacity and breathability, are the following:

ID	CONFIGURATION	PFE (%) ¹ Tolerance ± 5%	ΔP (Pa/cm ²) ² Tolerance ± 5%	BFE (%) ³ Tolerance ± 10%
16	UFI SMS-A	75	34	
9	Ahlstrom-munksjo SMS 70 gr/mq + Ahlstrom-munksjo SMS 70 gr/mq	82	50	95
18	Union Industries 40 gr/mq + UFI T4 + Union Industries 40 gr/mq	82	64	
19	Union Industries 40 gr/mq + UFI T4 + TNT 30 gr/mq	78	52	

22	Fitesa 40 gr/mq + UFI T4 + TNT 30 gr/mq	76	54	
23	Fitesa 40 gr/mq + UFI T6 + TNT 30 gr/mq	76	55	
20	Union Industries 40 gr/mq + UFI T6 + TNT 30 gr/mq	73	51	
17	Union Industries 40 gr/mq + Farè 25 gr/mq + Union Industries 40 gr/mq	70	55	
21	Fitesa 40 gr/mq + Farè 25 + Fitesa 40 gr/mq	68	58	
13	Fitesa SMS 40 gr/mq + Fitesa SMS 40 gr/mq + Fitesa 40 gr/mq	64	63	



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15	Union Industries 40 gr/mq + Union Industries 40 gr/mq + Union Industries 40 gr/mq	61	53	99
8	Ahlstrom-munksjo SMS 70 gr/mq	59	29	
3	Atex SMS 35 gr/mq + Atex SMS 35 gr/mq + Atex SMS 35 gr/mq	58	37	98
6	Atex SMS 35 gr/mq + Atex SMS 35 gr/mq	52	30	98
12	Fitesa SMS 40 gr/mq + Fitesa SMS 40 gr/mq	52	44	
7	SMSSMSSMS 90 gr/mq + SMSSMSSMS 90 gr/mq + SMSSMSSMS 90 gr/mq	49	33	
14	Union Industries 40 gr/mq + Union Industries 40 gr/mq	46	36	

- 1 Particle Filtration Efficiency (PFE) evaluates the material's filtration capacity. It is obtained by measuring particulate (aerosol) both upstream and downstream of the sample.
Class A materials: PFE \geq 65%
Class B materials: PFE \geq 50%
- 2 Pressure drop per surface unit (as specified in standard EN14683:2019).
Breathability value. Obtained by measuring the pressure difference through the sample.
Class A materials: $\Delta P \leq 40$ Pa/cm²
Class B materials: $\Delta P \leq 60$ Pa/cm²
- 3 Bacteria Filtration Efficiency (BFE) evaluates the material's filtration capacity with regards to bacteria. It is obtained by measuring CFU (colony forming units) both upstream and downstream of the sample.
Class A materials: BFE \geq 90%
Class B materials: BFE \geq 70%

When applying for approval to the ISS (Istituto Superiore di Sanità), the mask manufacturer shall also provide the following results:

- biocompatibility (responsibility of the material supplier)
- bioburden (as a first reference: info@abich.it)

As a reference parameter, certified materials used for surgical masks possess the following characteristics: pressure drop < 40 Pa/cm² or < 60 Pa/cm² according to their class. Particle Filtration Efficiency of certified surgical masks is between 50 - 70%.

Manufacturers of masks who select one of the configurations detailed here, are not required to submit the produced masks to Politecnico di Milano. They must request a copy of the results of the tests carried out on the material also tested by the Politecnico di Milano, directly from the companies supplying the material used.

It should be noted that the ISS (Istituto Superiore di Sanità) expresses a favourable opinion on the production and marketing of the product if, among other requirements, the company guarantees that production is implemented and managed according to a Quality Management System. The same guarantee must be provided by the producer of the raw material with special attention to the constancy of the characteristics of the product supplied.



Example of a generic “SURGICAL” mask’s production cycle

General description

SURGICAL masks are typically made up of at least 3 overlapping layers of nonwoven fabric having different functions (see above). The layers must, overall, have an adequate *meltblown* content (generally in excess of 20 g/m²) either in a single layer or as the sum of multiple layers. SMS type bonded nonwoven fabrics can be used.

Where necessary, use a multilayer made up of many layers, which can be mutually secured with glued points, as long as either food-grade or biomedical-grade adhesive is used. Conversely, other securing methods are not acceptable (e.g., needling, basting or any other method involving perforation of the fabric).

Sewing is naturally allowed along the perimeter.

Geometry and dimensions of the face mask

The shape of the SURGICAL mask must be appropriate to cover mouth and nose, and ensure a minimum “structure” (also conveyed by the presence of pleats) to avoid excessive adhesion to the face when inhaling. The typical face mask is rectangular, and is pleated on the short side, as illustrated in the images below. Pleats must face downwards to avoid build up of either dust or droplets in the hollows.

Then, the face mask has laces and nose pads (optional).

It can have a border created by applying a strip of additional material along the edge to facilitate sewing. It also enhances structure.



Fig. 1: Examples of a surgical mask

Materials required

LAYERS: as described above;

LACES: grosgrain elastic or grosgrain non-elasticated cotton;

NOSE PADS: metal or plastic (optional)

BORDER: optional. Polypropylene (if the border is heat-sealed)

Production and packaging cycle of face masks

The production cycle of face masks can be divided into 6 phases:

Phase 1 - Cut the layers

Phase 2 - Overlap the layers

Phase 3 - Pleat and border the mask



Phase 4 - Apply the laces

Phase 5 - Place in sachets (optional)

Phase 6 - Sterilize (optional)

Phase 1 - Cut the layers: layers can be cut using all cutting and bordering technological solutions widely adopted for fabrics in the textile and advanced technical materials industry: laser cutting plotter, water jet cutter, cutting dies, guillotine shears and scissors.

Phase 2 - Overlap the layers: layers can be either manually or automatically overlapped

Attention: Excessive calendaring pressure can compromise breathability

Phase 3 - Pleat and border the mask: using heat-sealing, ultrasonic welding or sewing

Phase 4 - Apply the laces: with heat-sealing, ultrasonic welding or sewing

Phase 5 - Place in sachets

Phase 6 - Sterilize (optional): gamma radiations, UV radiations, ethylene oxide, autoclave

Phase 1, phase 2 and phase 3 are typically closely interconnected: textile workshops might have industrial systems capable of overlapping several layers of material, cutting them, folding them (pleating) and bordering them at the same time.

Example (ONLY a rough indication)

CENTRAL BODY:

The face mask with dimensions 180mmx90mm (+5) can be obtained starting from a layered square with dimensions 180mmx180mm (+5mm) to be pleated according to the following diagram:

Pleating sequence starting from the top edge:

- 1) positive pleat 35 mm
- 2) negative pleat 48 mm
- 3) positive pleat 80 mm
- 4) negative pleat 97 mm
- 5) positive pleat 126 mm
- 6) negative pleat 142 mm

LACES:

There can be 2 types of laces

Type 1: 2 elastic bands, with adequate length, secured to the 2 corners of the face mask's short side (Fig. 1a).

Type 2: 4 cotton fabric laces or similar, with adequate length (NOT elastic), secured to the 4 corners of the face mask (Fig. 1a). Laces can be oriented as desired, in parallel with the short sides (as in the image) or in parallel with the long sides.

NOSE PADS:

the face mask can have a nose pad or nose clip secured at the centre of the mask's top edge. Material: plastic-coated metal; typical dimensions: 100 mm long, 3 mm wide.