

Medical face masks on the market: Review of materials, characteristics and performed tests

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1 Aim of the document

The aim of this document is to provide useful information for all subjects involved in the developing of surgical masks as medical devices in the effort to fight against the Covid-19 pandemic.

This document presents a market- based state of the art review in the field of manufacturing and testing of surgical face masks.

Information has been collected on the U.S.-FDA 510k database and statistically analysed in order to find out the actual best practices as regards face masks, their manufacturing development (materials and characteristics) and their testing for safety and efficacy.

This is a first exploit of the on-going research in progress at Eurofins Biolab S.r.l. in these field, while further deepening on this topic is under development.

2 Introduction

The transmission of infective agents during surgical procedures in operating theatres and other medical settings can occur in several ways. Sources are, for example, the noses and mouths of members of the surgical team. The main intended use of medical face masks is to protect the patient from infective agents and, additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations [1].

The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or molded between layers of fabric. Medical face mask are Class I medical devices.

The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness.

The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides. Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).

Medical face masks specified in EN 14683:2019+AC:2019 Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance. Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements [1].

3 Normative Requirement

In order to obtain market access, surgical face masks should satisfied the requirements of EN 14683:2019+AC:2019 "Medical face masks - Requirements and test methods"¹. This standard defines the tests that shall be performed to assess the safety and performance requirements of surgical masks.

¹ The previous version of the standard, EN 14683:2005 "Surgical masks - Requirements and test methods", is harmonized under Directive 93/42/EEC for Medical devices.

All the tests described in the standard shall be carried out on finished products or samples cut from finished products.

A short description of each test is reported below.

3.1 Bacterial filtration efficiency (BFE)

According to Annex B of EN 14683:2019, the BFE shall be tested as follows: a specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol. When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant Type, as described in Figure 1.

For thick and rigid masks such as rigid duckbills or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE.

When a mask consists of two or more areas with different characteristics or different layer composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.

3.2 Breathability

A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material. Test should be performed in accordance with the requirement of Annex C of EN 14683:2019 [1]. The differential pressure of the medical face mask shall conform to the value given for the relevant type, as described in Figure 1.

If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in EN European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).

3.3 Splash resistance

When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type II-R, as described in Figure 1 .

3.4 Microbial cleanliness (Bioburden)

When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Figure 1). This standard specifies requirements and provides guidance for the enumeration and microbial characterization of the population of viable microorganisms on or in a medical device, component, raw material or packaging [2].

To determine the mask's bioburden according to EN ISO 11737-1:2018, the producer can also refer to the procedure as described in Annex D of EN 14683:2019.

The number of masks that shall be tested is minimum 5 of the same batch/lot. In the test report, the total bioburden per individual mask shall be indicated, together with the total bioburden per gram based on the mask weight.

3.5 Biocompatibility

According to the definition and classification described in EN ISO 10993-1:2018, a medical face mask is a surface device with prolonged contact (more than 24 hours, less than 30 days), considering the cumulative application. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2018 and determine the applicable toxicology testing regime [3]. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request.

Test	Type I ^a	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm ²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

^a Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

Figure 1: Performance requirements for medical face masks [1].

4 Surgical face masks: data

The scope of this document is to provide information on the state of the art regarding the surgical face masks. Information included in this report covers the composition materials, the design characteristic and the requirements that this medical device shall satisfy.

To retrieve this information, a research has been performed on the FDA database of 510k submission of surgical facemask on March 19th, 2020, through a query in the FDA database for 510k submissions (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>) using the string “FXX” which is reported by FDA to be the product code identifying the surgical masks [4]. The submission reports related to the surgical facemasks submitted for 510k approval in the last ten years (January 2010 – now) have been included in the analysis.

The submission summaries contain information about:

- Component materials of the surgical mask: inner and outer layer, medium filter, nose clip and ear loops/ties;
- Dimensions;
- Conformity to U.S. regulation for surgical mask.

The evaluation of conformity for surgical mask in U.S.A. is based, among other, upon the following standards and related requirements:

- Fluid Resistance Performance Test according to ASTM F1862 with synthetic blood: The test is considered passed with respect to a pressure value (80, 120 or 160 mmHg) if at least 29 out of 32 samples pass the test at a specified pressure [5]. This test can be considered comparable with the Splash Resistance Pressure test described in EN 14683:2019 [1];
- Bacterial Filtration Efficiency test according to ASTM F2101: the test is considered passed if BFE is $\geq 98\%$; the results of this test are comparable with the results of BFE test performed according to EN 14683:2019 [1];
- Differential Pressure (Delta P) test according to MIL-M-36954C: the test is considered passed if the pressure difference ΔP is lower than 5 mmH₂O/cm². The results of this test are comparable with the results of the differential pressure test performed according to EN 14683:2019 [1].
- Biocompatibility evaluation performed according to ISO 10993-1:2018 “*Biological evaluation of medical devices Evaluation and testing within a risk management process*”. Surgical face mask may be categorized as surface medical device in contact with skin through a limited-contact (A, less than 24 hours) or prolonged contact (24 hours to 30 days) considering the cumulative application. According to this categorization, the biological endpoints to be assessed are cytotoxicity, irritation and sensitization together with chemical characterization as starting point for the evaluation [3].

5 Method

The 510k submission summary reports related to the period January 2010 – December 2019 (last submission date) have been exported from the database in CSV format and converted in an Excel file.

5.1 Constituent Materials

The component materials of each surgical face mask have been identified from the summary reports in order to assess which is the commonly used material for this medical device. Information about component materials of the following mask parts has been extracted from the submission report:

- inner layer (in contact with face skin);
- middle layer (which typically is the components that ensures the filtering properties);
- outer layer;
- era loops or tips;
- nose clip (if present);

The occurrence of material combination for the different device parts has been calculated in absolute and percentage values.

5.2 Performed Test

Information about performed test has been collected in the Excel file. Conversion factors between U.S.A. typical measure units and European typical measure units have been applied, in order to be able to compare the retrieved test results with the requirement of EN 14683:2019 [1] described in Figure 1. The following conversions have been performed:

- As regards the Fluid Resistance Performance Test, the results have been converted from mmHg to kPa;
- As regard the Differential Pressure test, the results have been converted from mmH₂O/cm² to Pa/cm².

The collected data have been analyzed and compared to materials combinations to identify possible correlations.

5.3 Biocompatibility

The 510k submission summaries have been analyzed to inquire if all submitted face masks meet the requirement of ISO 10993-1:2018, as described in §4.

5.4 Further information

Information about sterilization and classification of this medical device according to Directive 93/42/EEC1 [6] has been collected from the 510k submission summaries.

6 Results and discussions

The retrieved data are following described. It shall be taken in account that all the retrieved information comes from 510k submission summaries, which do not represents a source of sorted and homogeneous data. In some cases, data were missing or presented in non-univocally interpretable way. In this case, the summary has been excluded from the analysis with respect to a specific characteristic (e.g. material, performed test, etc.).

6.1 Constituent Materials

According to information reported in 33 out of 37 510k submission summaries, the constituent materials used for surgical masks production are:

- Polypropylene (PP);
- Polyethylene (PE);
- Cellulose;
- Polyolefin;
- Felt.

4 out of 37 submission summaries do not report information on the constituent materials.

The inner, middle and outer layers are mainly produced in PP, which results to be the mainly used component material for the production of surgical facemask. The second most used component materials is the combination of PE and PP. For further details, see Table 1, Table 2 and Table 3 together with Figure 2, Figure 3, Figure 4.

Material	Occurrence	Percentage
cellulose	3	9,09%
cellulose + polyolefin	1	3,03%
felt	1	3,03%
PP	23	69,70%
PP/PE	5	15,15%
Total	33	100,00%

Table 1: inner layer constituents

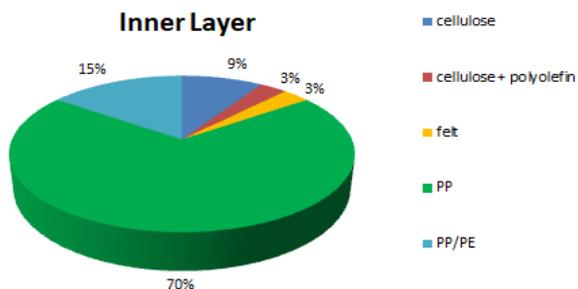


Figure 2: percentage distribution of inner layer constituents

Material	Occurrence	Percentage
cellulose + polyolefin	1	3,03%
felt	1	3,03%
PP	27	81,82%
PP/PE	4	12,12%
Total	33	100,00%

Table 2: middle layer constituents

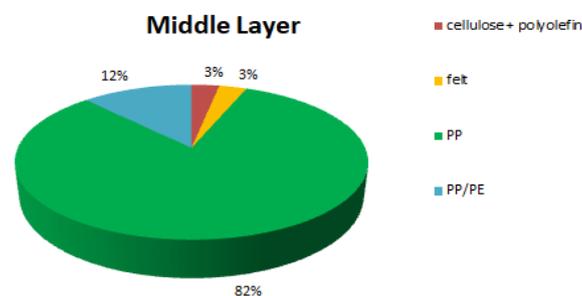


Figure 3: percentage distribution of middle layer constituents

Material	Occurrence	Percentage
cellulose + polyolefin	1	3,03%
felt	1	3,03%
polyolefin	2	6,06%
PP	26	78,79%
PP/PE	3	9,09%
Total	33	100,00%

Table 3: outer layer constituents

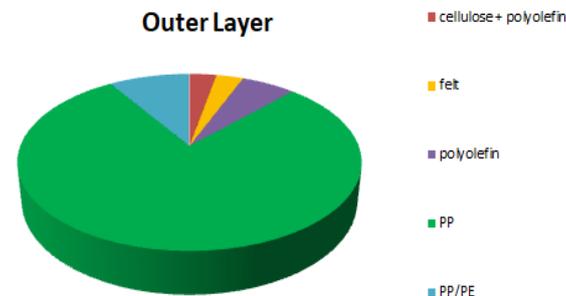


Figure 4: percentage distribution of inner layer constituents

6.2 Constituent Textures

Together with the component materials, information about the manufacturing/texture of the materials was retrieved on the 510k submission reports. A detailed summary of this information is reported in the following tables and figures. NW stands for “non woven”.

Texture	Occurrence	Percentage
cellulose	2	6,06%
felt	1	3,03%
NW cellulose	1	3,03%
NW PE blends and PP	2	6,06%
NW tissue + cellulose + polyolefin	1	3,03%
PP	4	12,12%
PP/PE	2	6,06%
NW PP/PE	1	3,03%
spunbond PP	19	57,58%
Total	33	100,00%

Table 4: inner layer texture

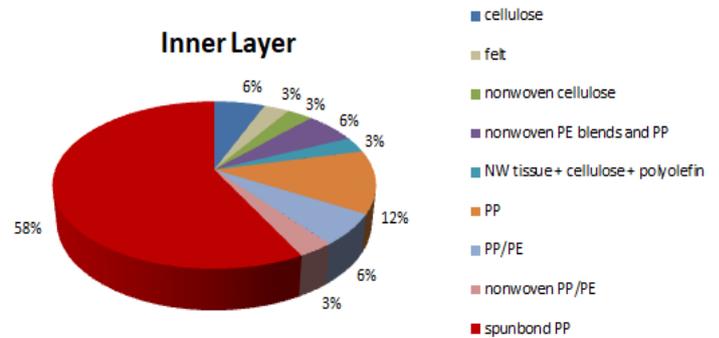


Figure 5: percentage distribution of inner layer textures

Texture	Occurrence	Percentage
felt	1	3,03%
meltblown PP	22	66,67%
NW PE blends and PP	2	6,06%
NW tissue + cellulose + polyolefin	1	3,03%
PP	1	3,03%
NW polyolefin melt blown + NW PP/PE blends	2	6,06%
meltblown PP + spunbond	4	12,12%
Total	33	100,00%

Table 5: middle layer texture

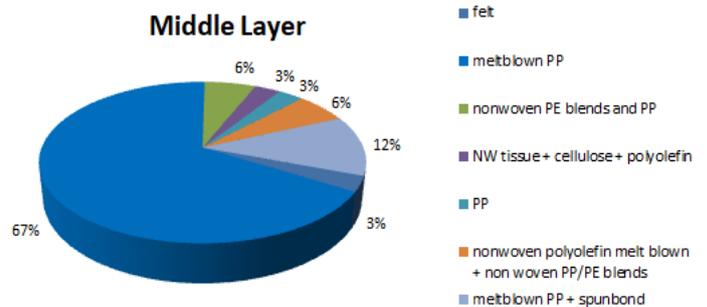


Figure 6: percentage distribution of middle layer textures

Texture	Occurrence	Percentage
felt	1	3,03%
nonwoven PE blends and PP	2	6,06%
NW tissue + cellulose + polyolefin	1	3,03%
PP	4	12,12%
PP/PE	1	3,03%
spunbond PP	22	66,67%
polyolefin spunbond	2	6,06%
Total	33	100,00%

Table 6: outer layer texture

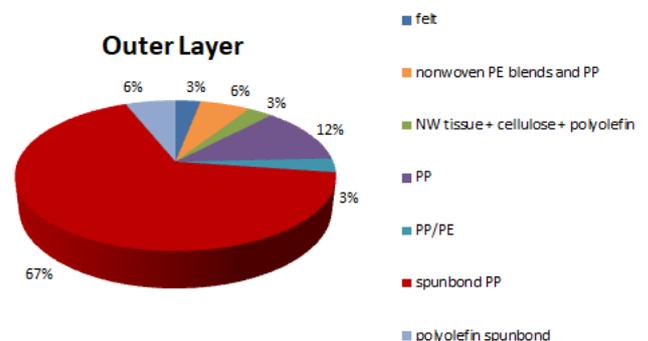


Figure 7: percentage distribution of outer layer textures

It came out the most used texture (54,55% occurrence) for surgical facemask is the so called "SMS" texture, consisting in:

- Spunbond PP for inner layer;
- Meltblown PP for middle layer;
- Spunbond PP for outer layer.

Spunbond PP has many excellent properties, strength and durability being just two of those. On the other hand, meltblown PP has relatively weak tensile properties but due to the smaller fibers and larger surface area taken up by the fibers, it has excellent wicking and barrier properties. So together, they can create a strong product which can also offer a barrier to fluids and particles.

6.3 Performed Tests

The results analysis has been focused on the SMS textured face masks, which are the 54,55% (19 out of 33 with information about component materials). Results of performed tests for SMS texture facemasks can be summarized as follows:

- The BFE is greater than 98% for 19 out of 19 (100%) of SMS facemasks, therefore this texture can be assumed to be in line for the requirement of EN 14683:2019 for Type I, Type II and Type IIR.
- The ΔP test result was provided for 17 out of 19 facemasks. 17 out of 17 gives ΔP lower than 60 Pa/cm² (EN 14683 requirement for Type IIR facemasks) and 12 out of 17 gives ΔP lower than 40 Pa/cm² (EN 14683 requirement for Type I and II facemasks).
- The splash test result gives value of at least 16 kPa for 16 out of 19 facemasks. 16 kPa is the EN 14683 requirement for Type IIR facemasks, while for Type I and Type II no specifics are fixed.

Therefore, it can be concluded that all the SMS textured facemask for which these results were provided in the 510k submission summaries, are in line with EN 14683 requirements for Type IIR facemasks.

6.4 Biocompatibility

30 out of 37 submission summaries contain information on tests performed for biocompatibility according to ISO 10993-1:2018 [3]. In all the 30 summaries the test item has been reported to pass the cytotoxicity, irritation and sensitization tests. In the other 7 submission reports, information about biocompatibility was missing. Therefore, all the materials used in the production of these facemasks can be considered biocompatible.

6.5 Further information

32 out of 37 submission summaries report that the evaluated surgical face mask is a Class II device according to FDA classification rules for medical devices. No information about classification was retrieved in the other 5 submission reports.

28 out of 37 submission summaries report that the evaluated surgical mask is intended to be sold non-sterile. 1 surgical mask is intended to be sterilized through Ethylene Oxide. 1 surgical mask can be provided sterile or not. No information about sterilization was retrieved in the other 7 submission reports. Almost all the surgical face masks analyzed are Class II (as per FDA classification) non-sterile medical devices.

7 Conclusion

The 510k submission summaries of surgical facemask related to period January 2010 – December 2019 have been analyzed.

As regards materials and textile features, it comes out that polypropylene is the mostly used material. Other materials are polyethylene, polyolefin and cellulose. The most used combination of materials and textures comes out to be the so called “SMS” consisting in:

- Spunbond PP for inner layer;
- Meltblown PP for middle layer;
- Spunbond PP for outer layer.

Spunbond PP has many excellent properties, strength and durability being just two of those. On the other hand, meltblown PP has relatively weak tensile properties but due to the smaller fibers and larger surface area taken up by the fibers, it has excellent wicking and barrier properties. So together, they can create a strong product which can also offer a barrier to fluids and particles. These results have been also compared with the indications described in a technical note published by Politecnico di Milano [7] regarding the recommended materials and characteristics for the manufacturing of surgical face masks. Through this comparison, the reliability of the present results was furtherly confirmed [7].

According to results obtained in the BFE, ΔP and Splash test it came out that all the SMS facemask are in line with EN 14683 requirement for Type IIR facemasks.

These results shall be observed with respect to the following facts:

- Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.
- Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements [1].
- Type II and especially Type IIR are to be considered the safe enough to be used by healthcare professionals in an operating room or in other medical settings with similar requirements [1].

Almost all the 37 analyzed facemasks are Class II (as per FDA classification) medical device, non-sterile and are conform to biocompatibility requirements of ISO 10993-1:2018. It is important to notice that in the European Union, surgical face mask are classified as medical device of Class I according to Directive 93/42/EEC.

8 Information sources and bibliography

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