Technical documentation according to Article 52 MDR (2017/745) Section 7 for medical face masks type II and IIR

Content

1. Product description and specification

1.1 Type II and IIR medical face masks are produced in accordance with the DIN EN 14683:2019-10 standard.

1.2 The product can be clearly identified by the imprint on the box: Company name, mask type, serial number, packaging quantity and user instructions are printed.

1.3 The users of the masks are both medical personnel and other groups of people. The masks are used in the medical environment to protect patients from infectious germs from the mouth and nose of medical personnel. In everyday life they are worn by other groups of people in order to reduce the risk of spreading infections.

1.4 The masks are classified as non-active medical devices. In the medical environment, the main use is to protect the patient against infectious germs from the mouths and noses of medical staff. In certain situations, the Type IIR medical face mask is used to protect the wearer against splashes of potentially contaminated liquids. In epidemic or pandemic situations, medical face masks can also be used to be worn by patients and other groups of people to reduce the risk of spreading infections.

1.5 It is a product that is manufactured in an automated mask production machine from three layers of fleece, an ear elastic band and a noseband wire.

1.6 The medical face masks are classified in risk class 1. The justification is based on the classification rule specified in the Medical Devices Ordinance (2017/745) Annex VIII Chapter III Paragraph 4.1; it is a non-invasive device.

1.7 The medical face mask consists of a filter fleece, which is embedded between a soft, anti-allergic fleece lying on the skin of the user and a protective fleece on the outside. The three layers are firmly joined together by the side seams. The movable nosepiece wire allows for adjustment to the shape of the user's face and prevents aerosol leakage and fogging of eyeglass lenses by providing an airtight seal at the top. The mask is attached to the head by the ear rubber bands.

Figure 1: medical face mask type II

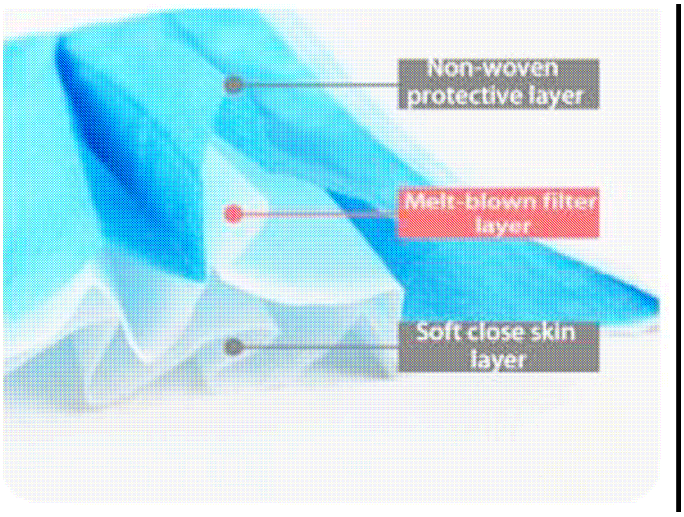

Figure 2: Structure of the medical face mask

1.8 The outer blue protective fleece is made of spunbonded polypropylene with a weight of 25 gr/m². The filter fleece consists of a meltblown microfibre fleece and has an air permeability of 190 l/m²/s. For the maximum filter effect this fleece is electrostatically charged. The inner spunbonded fleece, which lies on the skin of the user, is anti-allergic and consists of polypropylene spunbonded fleece with a weight of 25 gr/m².

Figure 3: Outer protective fleece

Figure 4: Filter fleece

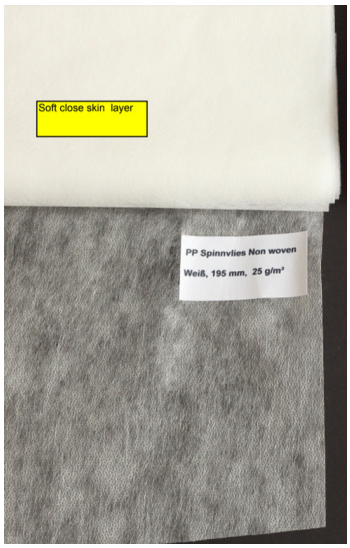

Figure 5: Inner fleece, hypoallergenic

1.9 Technical data of the outer protective fleece

Quality management DIN ISO 9001:2015	**Preliminary Data Sheet** **Date: 16.12.2019**

PP-PP

25 g/m² blue

Property	Test method	Unit	Value
weight	DIN EN 29073-1	g/m²	25
MD tensile strength CD	DIN EN 29073-3	N/5cm N/5cm	50 30
MD elongation CD	DIN EN 29073-3	% %	65 65
MD nail tear strength CD	DIN EN 12310-1	N N	30 50
water absoprtion	DIN 53923	%	--

The given technical values are based on the average of eight samples, taken across the whole production width and determined directly after the fabrication.
Test Parameters:
Determination of weight using samples with an area of 100 cm²
Determination of tensile strength and elongation using samples with a dimension of 5 cm x 25 cm
The test speed of the instrument is set to 500 mm/min in machine-direction (MD) and 500 mm/min in cross-direction (CD).

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1.10 Technical data of the filter fleece

AMF creation GmbH
Industriestr. 47
31275 Lehrte

Technisches Datenblatt / Technical Data Sheet

Produkt / Product: Meltblown

Produkteigenschaften / Typical Properties

Physikalische Eigenschaften / Physical Properties	Einheit / Unit	Mittelwert / Typical Average	Prüfmethode / Test Method	Toleranzen / Tolerances
Gewicht / Weight	(g / m²)	25	WSP 130.1	
Farbe / Colour		weiß / white		
Dehnung MD / Elongation MD	(%)	28	WSP 110.4	+ / - 2
Dehnung CD / Elongation CD	(%)	46	WSP 110.4	+ / - 2
Reissfestigkeit MD / Tensile strength MD	(N/5 cm)	17	WSP 110.4	+ / - 1
Reissfestigkeit CD / Tensile strength CD	(N/5cm)	13	WSP 110.4	+ / - 1
Luftdurchlässigkeit / Air Permeability	(l/m²/s)	190	WSP 70.1	+ / - 5 %

*Basis dieser technischen Werte sind Mittelwerte aus 8 Einzelwerten, verteilt über die Anlagenbreite, die direkt nach der Produktion bestimmt werden.
*These technical values are based on average values from 8 individual values, distributed over the width of the system, which are determined directly after production.

1.11 Technical data of the inner fleece

Quality management DIN ISO 9001:2015	**Preliminary Data Sheet** **Date: 16.12.2019**

PP-PP

25 g/m² white

Property	Test method	Unit	Value
weight	DIN EN 29073-1	g/m²	25
MD tensile strength CD	DIN EN 29073-3	N/5cm N/5cm	50 30
MD elongation CD	DIN EN 29073-3	% %	65 65
MD nail tear strength CD	DIN EN 12310-1	N N	30 50
water absoprtion	DIN 53923	%	--

The given technical values are based on the average of eight samples, taken across the whole production width and determined directly after the fabrication.
Test Parameters:
Determination of weight using samples with an area of 100 cm²
Determination of tensile strength and elongation using samples with a dimension of 5 cm x 25 cm
The test speed of the instrument is set to 500 mm/min in machine-direction (MD) and 500 mm/min in cross-direction (CD).

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1.12 Tabular summary of the properties of medical face masks:

Type	**Type II**	**Type IIR**

Bacterial filtration	> 98%	> 98%
Pressure difference	< 29.4%	< 49%
Resistance to		
Liquid splashes		yes
Intended use	External protection	External protection
Testing and certification	DIN EN 14683:2019-10	
Mask width approx. 75 mm	approx. 75 mm	
Length of the mask	approx. 195 mm	approx. 195 mm
Nonwoven 1st layer blue (nonwoven)	Polypropylene spunbond approx. 25 gr/m²	
Nonwoven 2nd layer white	Meltblown 25 gr/m²	
Nonwoven 3rd layer white	Polypropylene spunbond antiallergic 25 gr/m²	
Ear elastic band	Chilon and elastane 3 mm (diameter)	
Nose clip wire 0.45mm	single core approx. 3 mm with plastic sheathing wire thickness	

2. Information provided by the manufacturer

The masks are packed in cardboard boxes with 50 masks each. The boxes are printed with company name, mask type, packaging quantity and user instructions.

3. Information on design and manufacture

The masks were developed according to the specifications of DIN EN 14683:2019-10. They are manufactured exclusively under the responsibility of Negele & Faber GmbH, Bahnhofstraße 26 in 72138 Kirchentellinsfurt. Ongoing quality monitoring will be carried out by an independent institute to be named.

4. Essential safety and performance requirements

4.1 The medical masks meet the safety and performance requirements of DIN EN 14683:2019-10 and have been tested by an independent laboratory.

4.2 To prove conformity, the bacterial filter performance (BFE) was determined in percent. The nonwovens used were tested according to DIN EN 29073 Parts 1 and 3.

4.3 The following harmonized standards were applied:

- EN 14683:2019+AC: Medical face masks - Requirements and test methods; German version
- ISO 10993-1:2018-08: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- DIN EN ISO 9001:2015-11: Quality management systems – Requirements
- DIN EN 29073-1:1992-08: Textiles; test method for nonwovens; part 1: Determination of mass per unit area
- DIN EN 29073-3:1992-08: Textiles; test method for nonwovens; part 3: Determination of tensile strength and elongation

4.4 All test documents, data sheets on the materials used and quality assurance certificates are kept at the manufacturer Negele & Faber GmbH, Bahnhofstraße 26, 72138 Kirchentellinsfurt. The following documents can be viewed:

- Technical specifications of the mask production machine DY-KZJ120A
- Technical data sheet for nonwoven 1st layer blue, polypropylene spunbond approx. 25 gr/m² (nonwoven)
- Technical data sheet GmbH for the nonwoven 2nd layer white, meltblown 25 gr/m² from AMF creation
- Technical data sheet for nonwoven 3rd layer white, polypropylene spunbond antiallergic 25 gr/m²
- Test certificate according to DIN EN 14683:2019-10 on the bacterial filter performance by the laboratory A.B.I.C.H
- Quality certificate from the Ministry of Health for the A.B.I.C.H. Laboratory dated 21.06.2019

5. Risk-benefit analysis and risk management

The medical masks have been designed and manufactured so that they are suitable for their intended purpose under normal conditions of use. All known and foreseeable risks have been minimised as far as possible and are justifiable in comparison with the performance achieved for the user. The risks are minimised by regular inspections by an institute to be named and by providing the instructions for use on the packaging units.

6. Verification and validation

A certification according to DIN EN 14683:2019-10 was conducted by the independent laboratory

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