

BOX: 50 pcs

Dimensions: 15mm, 105mm, 59mm, 72mm, 15mm, 200mm, 105mm, 200mm, 105mm

Top Panel: 50 pcs, MASCARILLA QUIRURGICA IIR DESECHABLE, SURGICAL MASK IIR

Left Panel:

- CN logo
- CE, EN14683, ISO 13485, ISO 9001, ISO 14001
- Precauciones:
 - 1. Solo para un único uso. La reutilización del dispositivo puede causar infección cruzada o protección insuficiente.
 - 2. No lo reutilice después de sacarlo o desinfectarlo.
 - 3. Distinga correctamente la parte delantera y trasera de la mascarilla.
 - 4. Mantenga la mascarilla alejada de la cara y evite tocarla.
 - 5. Evite tocar la mascarilla con las manos.
 - 6. Manténgala alejada del fuego.
 - 7. No usar si es alérgico a latex o tejidos.

Center Panel:

- INSTRUCCIONES DE USO:**
 - Lavarse las manos con agua y jabón o frotárselas con una solución hidroalcohólica antes de manipular la mascarilla.
 - Identificar la parte superior de la mascarilla.
 - Colocar la mascarilla en la cara y ajustar la pinza nasal en la nariz.
 - Sostener la mascarilla desde el exterior y pasar el anteojo o anudarlo detrás de la misma, a ambos lados de las orejas, sin cruzarlas.
 - Bajar la parte inferior de la mascarilla a la barbilla y verificar que la mascarilla cubra la barbilla.
 - Refilzar la pinza nasal con ambos manos para ajustarla a la nariz y verificar que está colocada correctamente.
 - Una vez ajustada, no tocar la mascarilla con las manos.
- SURGICAL MASK IIR**
- Size: 17.5*9.5cm (BFE≥98%) (Pa/cm2<60)
- Type IIR according to EN 14683:2019
- Material Composition:
 - 3 Capas, Capa interna: PP non-woven (30%)
 - Capa intermedia: meltblown non-woven (30%)
 - Capa exterior: PP non-woven (30%)
 - Ajuste nariz: Alambre recubierto de PP (5%)
 - Elasticos orejas: Nylon-Spandex (5%)
- Medical Device
- Production License: MASCARILLA QUIRURGICA IIR DESECHABLE
- 50 pcs/box

Right Panel:

- USO PREVISTO:** Las mascarillas médicas deben usarse para proteger principalmente contra la propagación o transmisión de gérmenes infecciosos y agentes patógenos. El objetivo principal es proteger al paciente, y uno de los características observaciones de la mascarilla IIR es la protección adicional del usuario, que en ciertas situaciones se ve expuesto a salpicaduras de líquidos y microgotas potencialmente contaminantes y partículas viables.
- Protección de fluidos a pacientes y usuarios
- Suave y fácil de respirar
- No fabricado con látex de caucho natural

BAG: 10 pcs

Tipo IIR según EN 14683:2019

CE, ISO 13485, ISO 9001, ISO 14001, LOT, M, U, NON-STERILE

Distribuido por: CN logo, C/ Sofia, 3-5 - Pol. Ind. Cabezo Beaza 30353 Cartagena (Spain)

Algeza Green Tech Co., Ltd. Ave. No. 498, 263, Tiantai, Hangzhou Bay New Zone, Ningbo, Zhejiang, China.

INC. SPAIN: CN Comercial Beaza & Ortop. S.L. C/ Nueva Lapa nº 18 30005 Málaga - Spain

MADE IN CHINA (For clinical personnel to wear in the process of non-invasive operation)

MASCARILLA MÉDICA QUIRURGICA IIR DESECHABLE SURGICAL MASK IIR

Tamaño: 17.5*9.5cm (BFE≥98%) (Pa/cm2<60)

Tipo IIR según EN 14683:2019

Composición: 3 Capas, Capa interna: PP non-woven (30%), Capa intermedia: meltblown non-woven (30%), Capa exterior: PP non-woven (30%), Ajuste nariz: Alambre recubierto de PP (5%), Elasticos orejas: Nylon-Spandex (5%)

Dispositivo médico, Licencia de producción:

Instrucciones de uso:

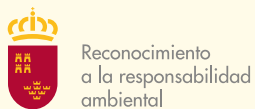
- Lavarse las manos con agua y jabón o frotárselas con una solución hidroalcohólica antes de manipular la mascarilla.
- Identificar la parte superior de la mascarilla.
- Colocar la mascarilla en la cara y ajustar la pinza nasal en la nariz.
- Sostener la mascarilla desde el exterior y pasar el anteojo o anudarlo detrás de la misma, a ambos lados de las orejas, sin cruzarlas.
- Bajar la parte inferior de la mascarilla a la barbilla y verificar que la mascarilla cubra la barbilla.
- Refilzar la pinza nasal con ambos manos para ajustarla a la nariz y verificar que está colocada correctamente.
- Una vez ajustada, no tocar la mascarilla con las manos.

Precauciones:

- Solamente para un único uso. La reutilización del dispositivo puede causar infección cruzada o protección insuficiente.
- No lo reutilice después de sacarlo o desinfectarlo.
- Distinga correctamente la parte delantera y trasera antes de usar.
- Por favor, preste atención a la fecha de vencimiento del producto antes de su uso.
- Desinfecte adecuadamente las mascarillas usadas de acuerdo con la política local de eliminación de desechos médicos.
- El dispositivo no debe usarse durante más de 24 horas.
- Manténgalo alejado del fuego.
- No usar si es alérgico a latex o tejidos.

10 uds

Colaboramos con



Asociaciones y Entidades a las que pertenecemos



| | | | |
|--|---------------------------|----------------------------|-----------|
| Ningbo Green Textile Co., Ltd. CE Technical Documentation | Document No.: CE-FM-03 | Edition: A0 | page: 1/2 |
| | Declaration of Conformity | Effective Date: 2020-05-04 | |

Manufacturer:

Name: Ningbo Green Textile Co., Ltd.

Add: No.498,3rd Xingci Road, Hangzhou Bay New Zone, Ningbo, Zhejiang, China 315336

Zip Code: 315300

European Representative:

CMC Medical Devices & Drugs S.L

C/Horacio Lengo N° 18

CP 29006, Málaga-Spain

Product Name: SURGICAL MASK IIR colors Blue and Pink

Model/size:

| Model | Size |
|-------------------|-------------------|
| SURGICAL MASK IIR | 175mm*95mm (±5mm) |

Classification and relevant Rule of MDD: class I, MDD 93/42/EEC Annex IX, Rule 1

Different models depend on the customer's specific requirements and no clinical manifestation difference.

The UMDNS code: 12458

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the premises of the manufacturer. Ningbo Green Textile Co., Ltd. is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES (MDD 93/42/EEC)



This Declaration of conformity is valid in connection with the release document for the respective batch of



| | | | |
|--------------------------------|---------------------------|----------------------------|-----------|
| Ningbo Green Textile Co., Ltd. | Document No.: CE-FM-03 | Edition: A0 | page: 2/2 |
| CE Technical Documentation | Declaration of Conformity | Effective Date: 2020-05-04 | |

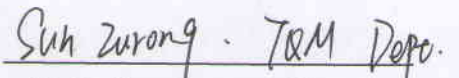
produced devices.

The above mention declaration of conformity is exclusively under the responsibility of

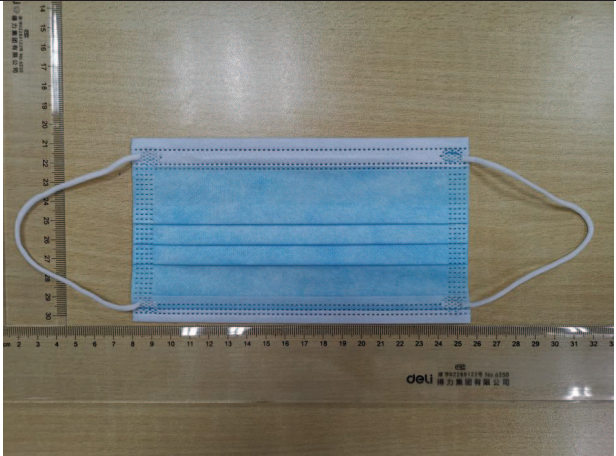


Company: Ningbo Green Textile Co., Ltd.

Address: No.498,3rd Xingci Road, Hangzhou Bay New Zone, Ningbo, Zhejiang, China 315336


Ningbo Zhejiang
Place, date 2020.5.16


Legally binding signature, Function



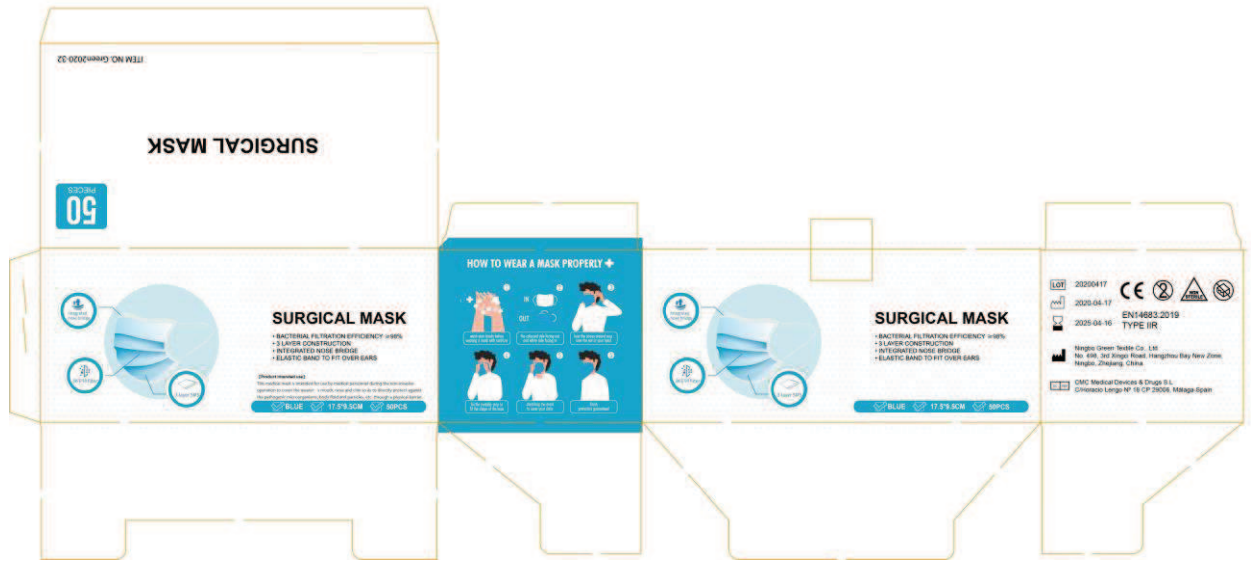
| | | | | |
|--|---|---|--|--------------------------------|
| Prüfbericht-Nr.: <i>Test report no.:</i> | 60406488 001 | Auftrags-Nr.: <i>Order no.:</i> | 244261377 | Seite 1 von 14 Page 1 of 14 |
| Kunden-Referenz-Nr.: <i>Client reference no.:</i> | 2254343 | Auftragsdatum: <i>Order date:</i> | 24.08.2020 | |
| Auftraggeber: <i>Client:</i> | Ningbo Green Textile Co., Ltd No. 498, 3rd Xingci Road, Hangzhou Bay New Zone, Ningbo, Zhejiang, China | | | |
| Prüfgegenstand: <i>Test item:</i> | Surgical Mask | | | |
| Bezeichnung / Typ-Nr.: <i>Identification / Type no.:</i> | Green2020-32 | | | |
| Auftrags-Inhalt: <i>Order content:</i> | Type test | | | |
| Prüfgrundlage: <i>Test specification:</i> | EN 14683:2019+AC:2019 (except for Clause 5.2.6 Biocompatibility) | | | |
| Wareneingangsdatum: <i>Date of sample receipt:</i> | 26.08.2020 |  | | |
| Prüfmuster-Nr.: <i>Test sample no.:</i> | A002896837-001 | | | |
| Prüfzeitraum: <i>Testing period:</i> | 27.08.2020 to 11.09.2020 | | | |
| Ort der Prüfung: <i>Place of testing:</i> | TÜV Rheinland (Shanghai) Co., Ltd. | | | |
| Prüflaboratorium: <i>Testing laboratory:</i> | TÜV Rheinland (Shanghai) Co., Ltd. | | | |
| Prüfergebnis*: <i>Test result*:</i> | Pass | | | |
| geprüft von: <i>tested by:</i> | Ranibow Pan  | genehmigt von: <i>authorized by:</i> | Xiaojun Ding  | |
| Datum: <i>Date:</i> | 17.09.2020 | Datum: <i>Date:</i> | 17.09.2020 | |
| Stellung / Position: | Sachverständige(r)/Expert | Stellung / Position: | Sachverständige(r)/Expert | |
| Sonstiges / Other: | The test report consists of EN 14683 test report including this cover page (14 pages). Clause 5.2.6 Biocompatibility is not evaluated in this report. | | | |
| Zustand des Prüfgegenstandes bei Anlieferung: <i>Condition of the test item at delivery:</i> | Prüfmuster vollständig und unbeschädigt <i>Test item complete and undamaged</i> | | | |
| * Legende: | P(ass) = entspricht o.g. Prüfgrundlage(n) | F(ail) = entspricht nicht o.g. Prüfgrundlage(n) | N/A = nicht anwendbar | N/T = nicht getestet |
| * Legend: | P(ass) = passed a.m. test specification(s) | F(ail) = failed a.m. test specification(s) | N/A = not applicable | N/T = not tested |
| Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. <i>This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.</i> | | | | |

| EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods | |
|--|--|
| Report Reference No. : | See cover page |
| Date of issue : | See cover page |
| Total number of pages : | See cover page |
| Testing Laboratory : | TÜV Rheinland (Shanghai) Co., Ltd. |
| Address : | No. 177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China |
| Applicant's name | Ningbo Green Textile Co., Ltd |
| Address : | No. 498, 3rd Xingci Road, Hangzhou Bay New Zone, Ningbo, Zhejiang, China |
| Test specification: | |
| Standard : | EN 14683:2019+AC:2019 |
| Test procedure : | Type test |
| Non-standard test method : | N/A |
| Test Report Form No. : | EN 14683:2019+AC:2019_B |
| Test Report Form Originator : | TÜV Rh (SZ) |
| Master TRF : | 2020-09 |
| Test item description : | Surgical Mask |
| Trade Mark | N/A |
| Manufacturer | Same as applicant |
| Model/Type reference | Green2020-32 |
| Classification : | Type IIR |

| List of Attachments (including a total number of pages in each attachment): | |
|---|---|
| N/A | |
| Summary of testing: | |
| Tests performed (name of test and test clause): Clause 5.2.2 Bacterial filtration efficiency; Clause 5.2.3 Breathability; Clause 5.2.4 Splash resistance; Clause 5.2.5 Microbial cleanliness | Testing location: TÜV Rheinland (Shanghai) Co., Ltd. No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China |

| Copy of marking plate |
|---|
| <p>The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.</p> <p>Box:</p> |

195x100x85mm
2020/08/18

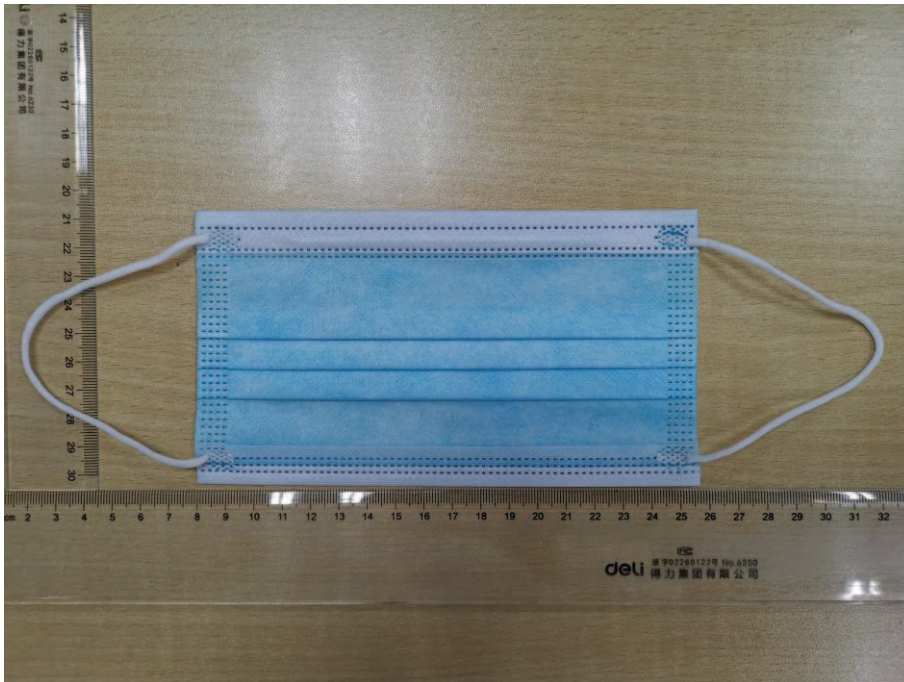


Package:

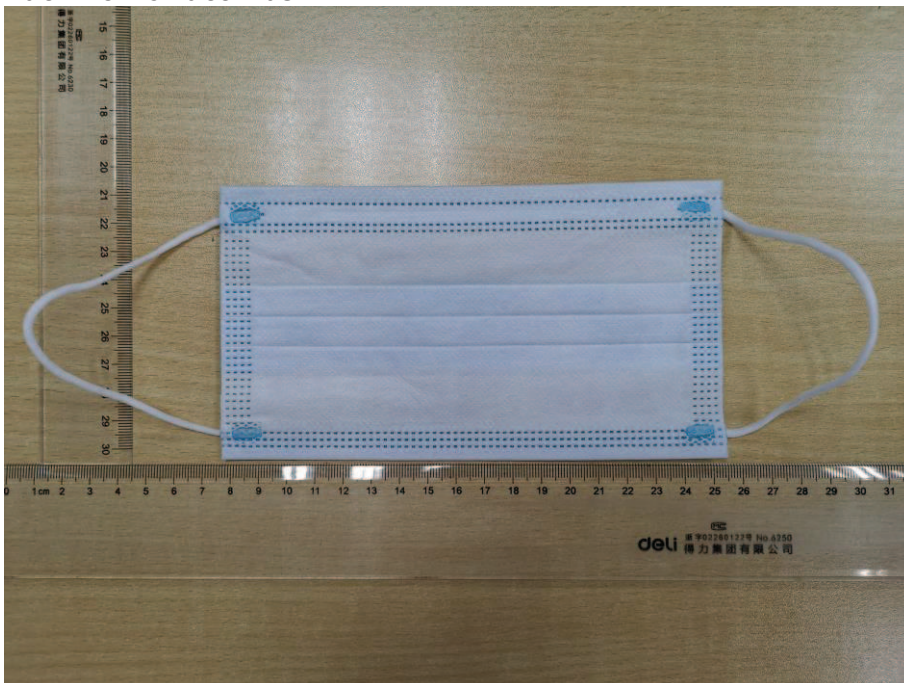
| | | | | |
|--------|--------|--------|--------|--------|
| | 520 mm | 390 mm | 520 mm | 390 mm |
| 340 mm | | | | |

Remark: According to information from applicant, there are 50pcs medical face masks including in final small package during mass production.

Front view of face mask:



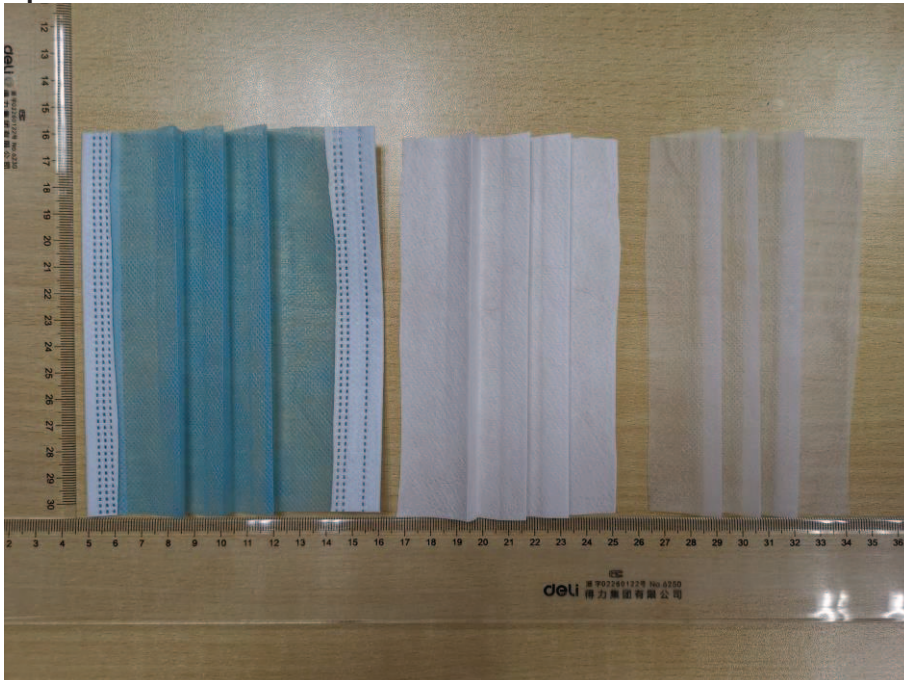
Back view of face mask:



Open view of face mask:



Open view of face mask:



| |
|---|
| <p>Testing</p> <p>Date of receipt of test item(s): See cover page</p> <p>Dates of tests performed.....: See cover page</p> |
| <p>Possible test case verdicts:</p> <ul style="list-style-type: none"> - test case does not apply to the test object : N/A - test object does meet the requirement : P (Pass) - test object was not evaluated for the requirement ... : N/E (collateral standards only) - test object does not meet the requirement : F (Fail) |
| <p>General remarks:</p> <p>"(See Attachment #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. The tests results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report.</p> <p>Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.</p> |
| <p>Name and address of factory (ies): Same as applicant</p> |
| <p>General product information:</p> <p>The submitted samples are type IIR, non-sterile surgical mask which are intended for use by medical personnel during the non-invasive operation to cover the wearer's mouth, nose and chin so as to directly protect against the pathogenic microorganisms, body fluid and particles, etc. through a physical barrier.</p> <p>Clause 5.2.6 Biocompatibility is not evaluated in this test report.</p> <p>The test results are for reference only. Relevant certification may be needed if the mask is intended to be sold in Europe.</p> |

| EN 14683:2019+AC:2019 | | | |
|-----------------------|--|---|------------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 4 | Classification | | P |
| | 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 IIR | P |
| 5 | Requirements | | P |
| 5.1 | General | | P |
| 5.1.1 | Materials and construction | | P |
| | The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. | Composed of a filter layer between layers of fabric | P |
| | The medical face mask shall not disintegrate, split or tear during intended use. | Complied | P |
| | In the selection of the filter and layer materials, attention shall be paid to cleanliness. | Considered | P |
| 5.1.2 | Design | | P |
| | 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. | Fitted closely over nose | P |
| | 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). | With a nose bridge | P |
| 5.2 | Performance requirements | | P |
| 5.2.1 | General | | P |
| | All tests shall be carried out on finished products or samples cut from finished products. | Complied | P |
| 5.2.2 | Bacterial filtration efficiency (BFE) | | P |
| | 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 in Table 1. | See appended table 5.2.2 | P |
| | For thick and rigid masks such as rigid duckbill 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. | Not thick and rigid mask | N/A |

| EN 14683:2019+AC:2019 | | | |
|-----------------------|--|---------------------------------------|------------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. | No such condition | N/A |
| | The lowest performing panel or area shall determine the BFE value of the complete mask | | N/A |
| 5.2.3 | Breathability | | P |
| | When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1. | See appended table 5.2.3 | P |
| | 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 this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s). | No such respiratory protective device | N/A |
| 5.2.4 | Splash resistance | | P |
| | 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 IIR in Table 1. | See appended table 5.2.4 | P |
| 5.2.5 | Microbial cleanliness (Bioburden) | | P |
| | When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 1). | See appended table 5.2.5 | P |
| 5.2.6 | Biocompatibility | | N/E |
| | According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact. | | N/E |
| | The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime. | | N/E |
| | The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. | | N/E |
| | The test results shall be available upon request. | | N/E |
| 6 | Marking, labelling and packaging | | P |
| | Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. | Checked and complied | P |
| | The following information shall be supplied: | | P |
| | a) number of this European Standard; | Marked on the label | P |

| EN 14683:2019+AC:2019 | | | |
|-----------------------|--|---------------------|----------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | b) type of mask (as indicated in Table 1). | Marked on the label | P |
| | EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered. | Considered | P |

| EN 14683:2019+AC:2019 | | | | | | | | |
|--|-------------------------------|--|---------------------------------|----------------------|---|--|---|----------|
| Clause | Requirement + Test | | | | | Result - Remark | | Verdict |
| 5.2.2 | | TABLE: Bacterial filtration efficiency (BFE) | | | | | | P |
| Batch/ lot no.: | Test Speci- men no.: | Dimension of the test specimen L x W (mm x mm) | test area (cm ²) | Flow rate (l/min) | Mean of the total plate counts of the two positive controls | Mean plate count of the negative controls | BFE for each test specimen (%) | Remarks |
| A00289 6837- 001 | 1 | 100×100 | 50 | 28.3 | 1838 | <1 | 99.9 | P |
| | 2 | 100×100 | 50 | 28.3 | 1838 | <1 | 99.9 | P |
| | 3 | 100×100 | 50 | 28.3 | 1838 | <1 | >99.9 | P |
| | 4 | 100×100 | 50 | 28.3 | 1838 | <1 | >99.9 | P |
| | 5 | 100×100 | 50 | 28.3 | 1838 | <1 | 99.9 | P |
| Supplementary information: | | | | | | | | |
| 1, Each specimen was conditioned at <u>21.0</u> °C and <u>85.0</u> % relative humidity for <u>4</u> h to bring them into equilibrium with atmosphere prior to testing. | | | | | | | | |
| 2, The side of the test specimen was facing towards the challenge aerosol: <u>face</u> | | | | | | | | |
| Remark: | | | | | | | | |
| Limit value: Type I ≥95%; Type II≥98%; Type IIR ≥98%. | | | | | | | | |

| 5.2.3 | | TABLE: Breathability (Differential pressure) | | | | P |
|------------------------|--|--|---|----------------------|---------|----------|
| Batch/ lot no.: | Test Specimen number- Test area number | Differential pressure for each test area (Pa/cm ²) | The averaged differential pressure for each test specimen (Pa/cm ²) | Flow rate (l/min) | Remarks | |
| A0028 96837- 001 | 1-1 | 39.3 | 39.3 | 8.0 | P | |
| | 1-2 | 42.5 | | 8.0 | P | |
| | 1-3 | 37.2 | | 8.0 | P | |
| | 1-4 | 39.4 | | 8.0 | P | |
| | 1-5 | 37.9 | | 8.0 | P | |
| | 2-1 | 41.5 | 37.9 | 8.0 | P | |
| | 2-2 | 35.1 | | 8.0 | P | |
| | 2-3 | 38.8 | | 8.0 | P | |
| | 2-4 | 39.3 | | 8.0 | P | |
| | 2-5 | 34.7 | | 8.0 | P | |
| | 3-1 | 44.5 | | 43.5 | 8.0 | P |

| EN 14683:2019+AC:2019 | | | | | |
|-----------------------|--------------------|------|-----------------|---------|---|
| Clause | Requirement + Test | | Result - Remark | Verdict | |
| | 3-2 | 43.3 | | 8.0 | P |
| | 3-3 | 47.4 | | 8.0 | P |
| | 3-4 | 43.3 | | 8.0 | P |
| | 3-5 | 39.0 | | 8.0 | P |
| | 4-1 | 44.3 | 43.2 | 8.0 | P |
| | 4-2 | 40.3 | | 8.0 | P |
| | 4-3 | 40.8 | | 8.0 | P |
| | 4-4 | 45.4 | | 8.0 | P |
| | 4-5 | 45.3 | | 8.0 | P |
| | 5-1 | 47.3 | 43.9 | 8.0 | P |
| | 5-2 | 47.6 | | 8.0 | P |
| | 5-3 | 41.0 | | 8.0 | P |
| | 5-4 | 45.0 | | 8.0 | P |
| | 5-5 | 38.7 | | 8.0 | P |

Supplementary information:

Each specimen was conditioned at 21.0 °C and 85.0 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.

Remark:

Limit value: Type I <40; Type II <40; Type IIR <60.

| 5.2.4 | TABLE: Splash resistance | | | | P |
|-----------------|--------------------------|--------------------------------------|-------------------------|---------|---|
| Batch/ lot no.: | Test mask no.: | The material of tested mask | Test result (Pass/fail) | Remarks | |
| A002896837-001 | 1 | Polypropylene fused jet filter layer | Pass | -- | |
| | 2 | Polypropylene fused jet filter layer | Pass | -- | |
| | 3 | Polypropylene fused jet filter layer | Pass | -- | |
| | 4 | Polypropylene fused jet filter layer | Pass | -- | |
| | 5 | Polypropylene fused jet filter layer | Pass | -- | |
| | 6 | Polypropylene fused jet filter layer | Pass | -- | |
| | 7 | Polypropylene fused jet | Pass | -- | |

| EN 14683:2019+AC:2019 | | | | |
|-----------------------|--------------------------------------|-----------------|---------|--|
| Clause | Requirement + Test | Result - Remark | Verdict | |
| | filter layer | | | |
| 8 | Polypropylene fused jet filter layer | Pass | -- | |
| 9 | Polypropylene fused jet filter layer | Pass | -- | |
| 10 | Polypropylene fused jet filter layer | Pass | -- | |
| 11 | Polypropylene fused jet filter layer | Pass | -- | |
| 12 | Polypropylene fused jet filter layer | Pass | -- | |
| 13 | Polypropylene fused jet filter layer | Pass | -- | |
| 14 | Polypropylene fused jet filter layer | Pass | -- | |
| 15 | Polypropylene fused jet filter layer | Pass | -- | |
| 16 | Polypropylene fused jet filter layer | Pass | -- | |
| 17 | Polypropylene fused jet filter layer | Pass | -- | |
| 18 | Polypropylene fused jet filter layer | Pass | -- | |
| 19 | Polypropylene fused jet filter layer | Pass | -- | |
| 20 | Polypropylene fused jet filter layer | Pass | -- | |
| 21 | Polypropylene fused jet filter layer | Pass | -- | |
| 22 | Polypropylene fused jet filter layer | Pass | -- | |
| 23 | Polypropylene fused jet filter layer | Pass | -- | |
| 24 | Polypropylene fused jet filter layer | Pass | -- | |
| 25 | Polypropylene fused jet filter layer | Pass | -- | |
| 26 | Polypropylene fused jet filter layer | Pass | -- | |
| 27 | Polypropylene fused jet filter layer | Pass | -- | |

| EN 14683:2019+AC:2019 | | | | |
|--|--------------------|--------------------------------------|-----------------|---------|
| Clause | Requirement + Test | | Result - Remark | Verdict |
| | 28 | Polypropylene fused jet filter layer | Pass | -- |
| | 29 | Polypropylene fused jet filter layer | Pass | -- |
| | 30 | Polypropylene fused jet filter layer | Pass | -- |
| | 31 | Polypropylene fused jet filter layer | Pass | -- |
| | 32 | Polypropylene fused jet filter layer | Pass | -- |
| Supplementary information: 1, Each specimen was conditioned at <u>21.0</u> °C and <u>85.0</u> % relative humidity for <u>4</u> h to bring them into equilibrium with atmosphere prior to testing. 2, The description of target area tested: <u>the center of outside</u> 3, Any technique used to enhance visual detection of synthetic blood: <u>none</u> 4, The temperature and relative humidity for testing: <u>21.0</u> °C and <u>85.0</u> % 5, Description of any pre-treatment techniques used: <u>constant temperature and humidity machine was used</u> | | | | |
| Remark: Limit value: not required for Type I and Type II; Type IIR ≥16,0. | | | | |

| 5.2.5 | TABLE: Microbial cleanliness (Bioburden) | | | | P |
|--|--|-------------------------|---|----------------------------------|---------|
| Batch/ lot no.: | Mask(under test) no.: | Weight of each mask (g) | Total bioburden per individual mask (CFU) | Total bioburden per gram (CFU/g) | Remarks |
| A00289683 7-001 | 1 | 3.12 | 23.4 | 7.5 | P |
| | 2 | 3.15 | 15.6 | 5.0 | P |
| | 3 | 3.13 | 19.5 | 6.2 | P |
| | 4 | 3.16 | 24.7 | 7.8 | P |
| | 5 | 3.12 | 31.2 | 10.0 | P |
| Supplementary information: Remark: Limit value: Type I ≤30; Type II ≤30; Type IIR ≤30. | | | | | |

End of test report