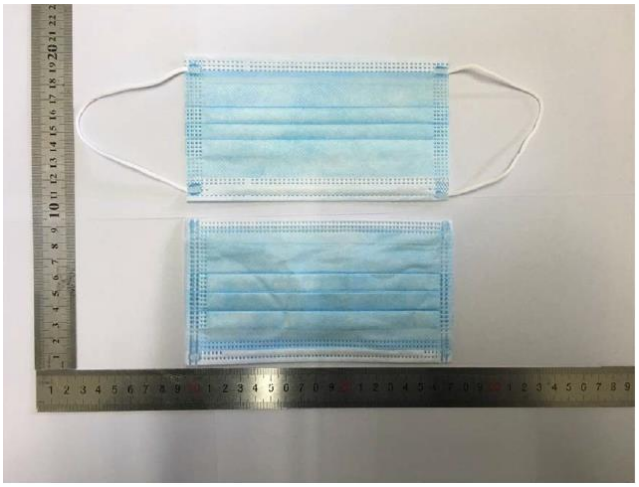
| | | | | |
|---|---|---|---|---|
| **Prüfbericht-Nr.:** *Test Report No.*: | **60383870 001** | **Auftrags-Nr.:** *Order No.*: | **190126807** | Seite 1 von 14 *Page 1 of 14* |
| **Kunden-Referenz-Nr.:** *Client Reference No.*: | **2254805** | **Auftragsdatum:** *Order date*: | **2020-06-15** | |

| | |
|---|---|
| **Auftraggeber:** *Client*: | **Equipment Co., Ltd.** Business Park, Dingluan Town, Changyuan County |
| **Prüfgegenstand:** *Test item*: | **Disposable Surgical Mask** |
| **Bezeichnung / Typ-Nr.:** *Identification / Type No.*: | **Plane type Large** |
| **Auftrags-Inhalt:** *Order content*: | **Type test** |
| **Prüfgrundlage:** *Test specification*: | **EN 14683:2019+AC:2019(except for Clause 5.2.6 Biocompatibility)** |
| **Wareneingangsdatum:** *Date of receipt*: | **2020-05-20** |
| **Prüfmuster-Nr.:** *Test sample No.*: | **Engineering sample** |
| **Prüfzeitraum:** *Testing period*: | **2020-05-20 to 2020-06-04** |
| **Ort der Prüfung:** *Place of testing*: | **See page 3** |
| **Prüflaboratorium:** *Testing laboratory*: | **TÜV Rheinland (China) Ltd.** |
| **Prüfergebnis*:** *Test result**: | **Pass** |



**geprüft von /** *tested by*: Mengdi Zhang

| **Datum** *Date* | **Name / Stellung** *Name / Position* | **Unterschrift** *Signature* |
|---|---|---|
| 2020-06-16 | Mengdi Zhang / Project Engineer | |

**kontrolliert von /** *reviewed by*: Han Dong

| **Datum** *Date* | **Name / Stellung** *Name / Position* | **Unterschrift** *Signature* |
|---|---|---|
| 2020-06-16 | Han Dong / Reviewer | |

**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:** Prüfmuster vollständig und unbeschädigt
*Condition of the test item at delivery*: *Test item complete and undamaged*

| | | | | | |
|---|---|---|---|---|---|
| * Legende: | 1 = sehr gut | 2 = gut | 3 = befriedigend | 4 = ausreichend | 5 = mangelhaft |
| | P(ass) = entspricht o.g. Prüfgrundlage(n) | | F(ail) = entspricht nicht o.g. Prüfgrundlage(n) | N/A = nicht anwendbar | N/T = nicht getestet |
| *Legend:* | *1 = very good* | *2 = good* | *3 = satisfactory* | *4 = sufficient* | *5 = poor* |
| | *P(ass) = passed a.m. test specification(s)* | | *F(ail) = failed a.m. test specification(s)* | *N/A = not applicable* | *N/T = not tested* |

| **EN 14683:2019+AC: 2019<br>Medical face masks —<br>Requirements and test methods** | |
|---|---|
| **Report Reference No. ..... :** | **60383870 001** |
| **Date of issue..... :** | See cover page |
| **Total number of pages ..... :** | See cover page |
| **Testing Laboratory ..... :** | **TÜV Rheinland (China) Ltd.** |
| **Address..... :** | Unit 707, AVIC Building, No. 10B, Central Road, East 3rd Ring Road,Chaoyang District, Beijing 100022, P,R,China |
| **Applicant's name ..... :** | **Henan Zhongjian Medical Equipment Co., Ltd.** |
| **Address..... :** | Business Park, Dingluan Town, Changyuan County |
| **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_A |
| **Test Report Form Originator ..... :** | TÜV Rh (SZ) |
| **Master TRF ..... :** | 2020-03 |
| **Test item description..... :** | **Disposable Surgical Mask** |
| **Trade Mark..... :** | 豫中健 YUZHONGJIAN |
| **Manufacturer ..... :** | **Equipment Co., Ltd.**<br>Business Park, Dingluan Town, Changyuan County |
| **Model/Type reference..... :** | **Plane type Large** |
| **Classification..... :** | Type IIR |

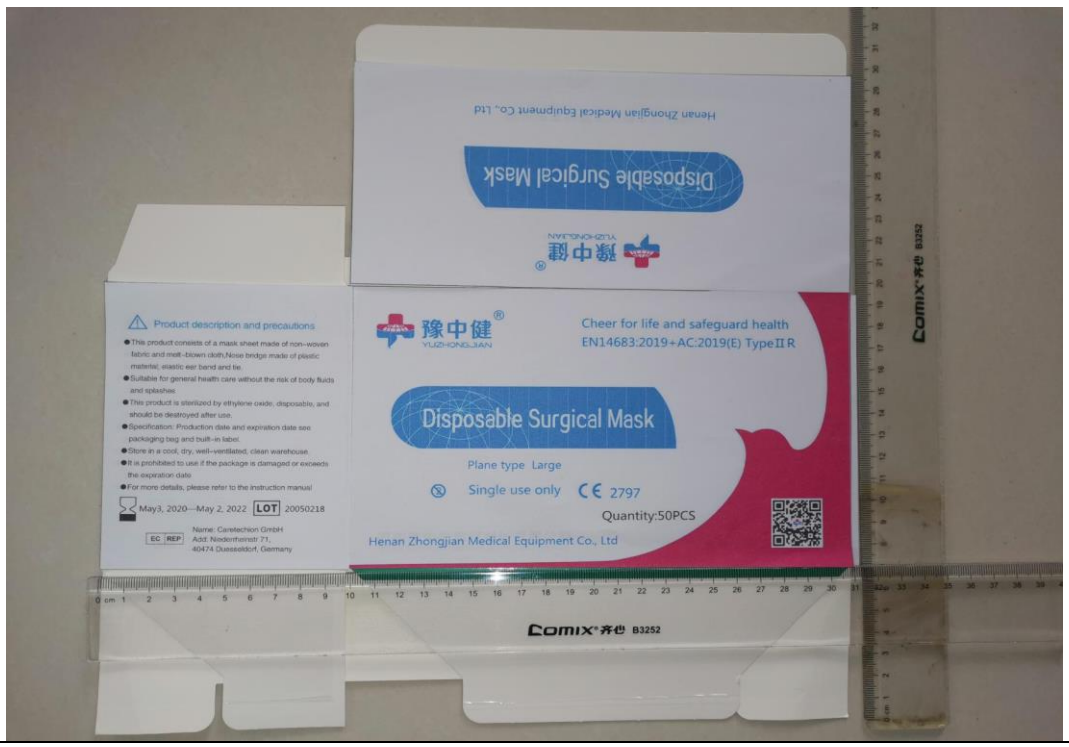
| **List of Attachments (including a total number of pages in each attachment):** | |
|---|---|
| None | |
| **Summary of testing:** | |
| **Tests performed (name of test and test clause):**<br>**Clause 5.1.1 Materials and construction**<br>**Clause 5.1.2 Design** | **Testing location:**<br>**TÜV Rheinland (China) Ltd.**<br>Unit 707, AVIC Building, No. 10B, Central Road, East 3rd Ring Road,Chaoyang District, Beijing 100022, P,R,China |
| **Clause 5.2.2: Bacterial filtration efficiency (BFE)**<br>**Clause 5.2.3: Breathability**<br>**Clause 5.2.4: Splash resistance**<br>**Clause 5.2.5: Microbial cleanliness (Bioburden)**<br><br>**Note: All tests listed as above have been conducted in the competent external lab under the supervision of a TUV engineer** | **Pony Testing Group Shanghai Co.,Ltd.**<br>2/3/4/6/F., Building 35, No.680, Guiping Road, Xuhui District, Shanghai, China |

**Copy of marking plate**

**The artwork below may be only a draft.**

**Label:**

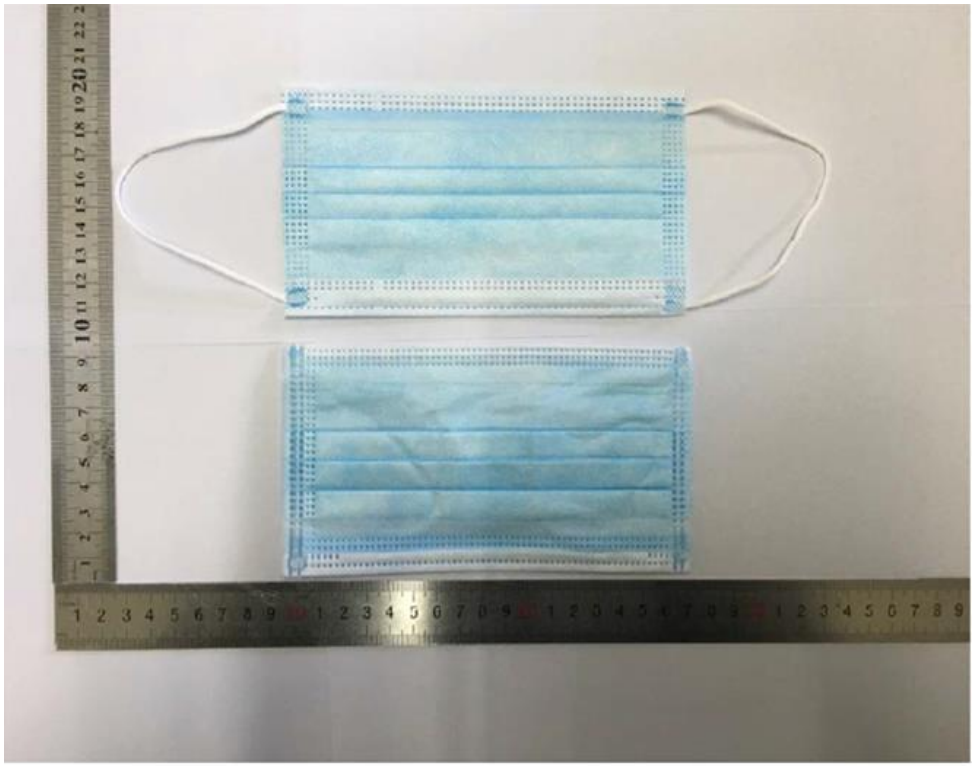

**Box:**



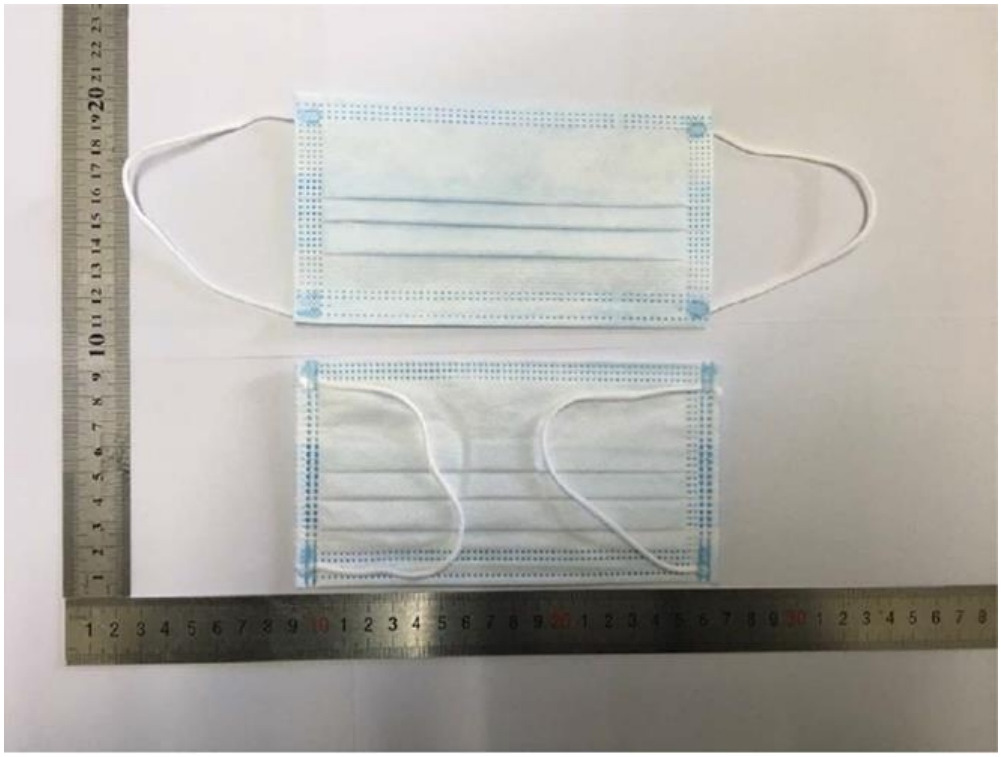
**Box:**


**Back view of package:**

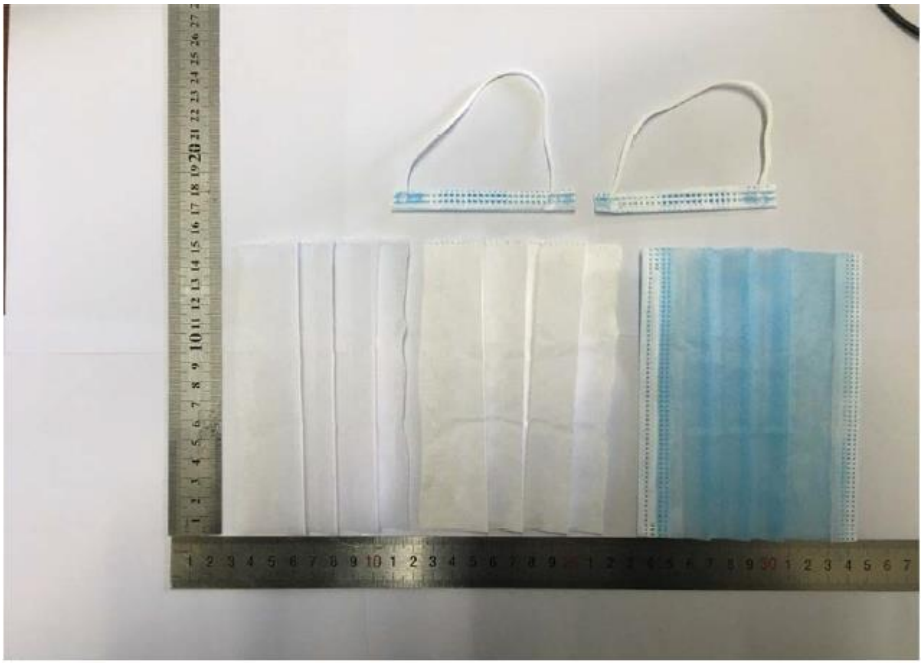
**Front view of face mask:**



**Back view of face mask:**



**Open view of face mask:**



| | |
|---|---|
| **Date of receipt of test item(s).....:** | See cover page |
| **Dates of tests performed .....:** | See cover page |

**Possible test case verdicts:**

| | |
|---|---|
| - 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) |

**General remarks:**

"(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.

**Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**

| | |
|---|---|
| **Name and address of factory (ies) ..... :** | **Equipment Co., Ltd.** Business Park, Dingluan Town, Changyuan County |

**General product information:**

The submitted samples are type IIR, the Disposable Surgical Mask which is applicable to the basic protection of medical personnel or related personnel, as well as the protection against the spread of body fluids and splashes in the process of invasive operation. It is a sterile product.

Clause 5.2.6 Biocompatibility is not evaluated in this test report.

The test results are for reference only. Relevant certification may be needed if the mask is intended to be sold in Europe.

| 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. | Nonwovens, melt blown fabrics and plastic materials, elastic materials | 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. | Complied | 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 nose clip. | 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. | | 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 1.1 1.2. | The Bacterial Filtration Efficiency ≥ 98%<br>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 such masks | N/A |
| | When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. | | N/A |

| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | 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 2.1 2.2. | The differential pressure <60Pa/cm$^2$<br>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 provided | 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 3.1 3.2). | The bioburden of the medical mask was ≤30 CFU/g<br>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. | Not evaluated in this test report. | 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<br>Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. | Considered | P |
| | The following information shall be supplied: | | P |
| | a) number of this European Standard; | EN 14683:2019 Marked on the label | P |
| | b) type of mask (as indicated in Table 1). | Type IIR Marked on the label | P |
| | EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered. | Compliance | 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** |
| **20050218** | **1** | **155×125** | **63.6** | **28.3** | **2005** | **0** | **＞99.9** | **≥98** |
| | **2** | **155×125** | **63.6** | **28.3** | **2005** | **0** | **99.9** | **≥98** |
| | **3** | **155×125** | **63.6** | **28.3** | **2005** | **0** | **99.9** | **≥98** |
| | **4** | **155×125** | **63.6** | **28.3** | **2005** | **0** | **＞99.9** | **≥98** |
| | **5** | **155×125** | **63.6** | **28.3** | **2005** | **0** | **99.9** | **≥98** |

Supplementary information:
1, Each specimen was conditioned at 21.3 °C and 85.0 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
2, The side of the test specimen was facing towards the challenge aerosol: inside of mask

| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| **5.2.3** | **TABLE: Breathability(Differential pressure)** | | | | **P** |
|---|---|---|---|---|---|
| **Batch/ lot no.:** | **Test Specimen number-Test area number** | **Differential pressure for each test area (Pa/cm²)** | **The averaged differential pressure for each test specimen (Pa/cm²)** | **Flow rate (l/min)** | **Remarks** |
| **20050218** | **1-1** | **35.7** | **34.9** | **8** | **<60** |
| | **1-2** | **34.0** | | **8** | **<60** |
| | **1-3** | **34.0** | | **8** | **<60** |
| | **1-4** | **36.2** | | **8** | **<60** |
| | **1-5** | **34.7** | | **8** | **<60** |
| | **2-1** | **35.7** | **35.7** | **8** | **<60** |
| | **2-2** | **36.5** | | **8** | **<60** |
| | **2-3** | **35.2** | | **8** | **<60** |
| | **2-4** | **34.3** | | **8** | **<60** |
| | **2-5** | **36.9** | | **8** | **<60** |
| | **3-1** | **44.4** | **44.5** | **8** | **<60** |
| | **3-2** | **45.1** | | **8** | **<60** |
| | **3-3** | **42.6** | | **8** | **<60** |
| | **3-4** | **45.0** | | **8** | **<60** |
| | **3-5** | **45.2** | | **8** | **<60** |
| | **4-1** | **35.7** | **36.1** | **8** | **<60** |
| | **4-2** | **34.2** | | **8** | **<60** |
| | **4-3** | **37.1** | | **8** | **<60** |
| | **4-4** | **37.6** | | **8** | **<60** |
| | **4-5** | **35.9** | | **8** | **<60** |
| | **5-1** | **40.4** | **39.3** | **8** | **<60** |
| | **5-2** | **38.8** | | **8** | **<60** |
| | **5-3** | **38.6** | | **8** | **<60** |
| | **5-4** | **38.6** | | **8** | **<60** |
| | **5-5** | **40.1** | | **8** | **<60** |

**Supplementary information:**

Each specimen was conditioned at 21.0 °C and 84.0 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.

| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| **5.2.4** | **TABLE: Splash resistance** | | | **P** |
|---|---|---|---|---|
| **Batch/ lot no.:** | **Test mask no.:** | **The material of tested mask** | **Test result (Pass/fail)** | **Remarks** |
| **20050218** | **1** | **Nonwovens, melt blown fabrics** | **Pass** | **-** |
| | **2** | | **Pass** | **-** |
| | **3** | | **Pass** | **-** |
| | **4** | | **Pass** | **-** |
| | **5** | | **Pass** | **-** |
| | **6** | | **Pass** | **-** |
| | **7** | | **Pass** | **-** |
| | **8** | | **Pass** | **-** |
| | **9** | | **Pass** | **-** |
| | **10** | | **Pass** | **-** |
| | **11** | | **Pass** | **-** |
| | **12** | | **Pass** | **-** |
| | **13** | | **Pass** | **-** |
| | **14** | | **Pass** | **-** |
| | **15** | | **Pass** | **-** |
| | **16** | | **Pass** | **-** |
| | **17** | | **Pass** | **-** |
| | **18** | | **Pass** | **-** |
| | **19** | | **Pass** | **-** |
| | **20** | | **Pass** | **-** |
| | **21** | | **Pass** | **-** |
| | **22** | | **Pass** | **-** |
| | **23** | | **Pass** | **-** |
| | **24** | | **Pass** | **-** |
| | **25** | | **Pass** | **-** |
| | **26** | | **Pass** | **-** |
| | **27** | | **Pass** | **-** |
| | **28** | | **Pass** | **-** |
| | **29** | | **Pass** | **-** |
| | **30** | | **Pass** | **-** |
| | **31** | | **Pass** | **-** |

| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | | |
|---|---|---|---|---|
| | **32** | | **Pass** | **-** |

**Supplementary information:**

1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 18 h to bring them into equilibrium with atmosphere prior to testing.
2, The description of target area tested: the centre of the specimen
3, Any technique used to enhance visual detection of synthetic blood: cotton absorbent swab
4, The temperature and relative humidity for testing: 21 °C and 80 %
5, Description of any pre-treatment techniques used:\

| **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/g)** | **Remarks** |
| **20050218** | **1** | **3.33** | **23** | **≤30** |
| | **2** | **3.35** | **8** | **≤30** |
| | **3** | **3.34** | **14** | **≤30** |
| | **4** | **3.32** | **4** | **≤30** |
| | **5** | **3.33** | **12** | **≤30** |

**Supplementary information:**

**END OF TEST REPORT**