

## Personal protection equipment

### KN95 PM2.5

rev. 8



| Code    | Description                        |   |
|---------|------------------------------------|---|
| KN95-CE | KN95 disposable face mask, CE mark | CE certificate n. 0P20031.TYUQ21 / ECM dated 16/03/2020 – valid till 15/03/2025<br>Tech construction file n. TPHB20031222272<br>EN149:2001+A1:2009   CE Directive R2016/425 |
|         | Packing                            | Individually packed units   50 units per bag   20 bags or 1000 units per carton   9 kg per carton<br>68*32*61 cm  |
|         | Storage temperature range          | -20°C to +30°C  |
|         | Storage relative humidity range    | < 80%   |
|         | Shelf life                         | Three years from manufacturing date   |
|         | HSCODE                             | 6307900000  |
|         | Standard compliance                | KN95 (GB2626-2006) equivalent to FFP2 (EN 149-2001) – see below   |

E&OE

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<https://medical.greensley.eu> | [info@greensley.eu](mailto:info@greensley.eu)

## CERTIFICATION EQUIVALENCE

Based on this comparison, it is reasonable to consider China KN95, AS/NZ P2, Korea 1st Class, and Japan DS FFRs as "equivalent" to US NIOSH N95 and European FFP2 respirators, for filtering non-oil-based particles such as those resulting from wildfires, PM 2.5 air pollution, volcanic eruptions, or bioaerosols (e.g. viruses). However, prior to selecting a respirator, users should consult their local respiratory protection regulations and requirements or check with their local public health authorities for selection guidance.

| Certification/<br>Class<br>(Standard)  | N95<br>(NIOSH-42C<br>FR84) | FFP2 (EN<br>149-2001)   | KN95<br>(GB2626-20<br>06)            | P2 (AS/NZ<br>1716:2012)                                | Korea 1 <sup>st</sup><br>Class<br>(KMOEL -<br>2017-64) | DS (Japan<br>JMHLW-<br>Notification<br>214, 2018)                  |
|--|----------------------------|---|--------------------------------------|--|--|--|
| Filter performance –<br>(must be ≥ X%<br>efficient)  | ≥ 95%                      | ≥ 94%   | ≥ 95%                                | ≥ 94%  | ≥ 94%  | ≥ 95%  |
| Test agent   | NaCl                       | NaCl and<br>paraffin oil  | NaCl                                 | NaCl   | NaCl and<br>paraffin oil                               | NaCl   |
| Flow rate  | 85 L/min                   | 95 L/min  | 85 L/min                             | 95 L/min   | 95 L/min   | 85 L/min   |
| Total inward<br>leakage (TIL)* –<br>tested on<br>human subjects<br>each<br>performing<br>exercises | N/A                        | ≤ 8% leakage<br>(arithmetic<br>mean)  | ≤ 8% leakage<br>(arithmetic<br>mean) | ≤ 8% leakage<br>(individual and<br>arithmetic<br>mean) | ≤ 8% leakage<br>(arithmetic<br>mean)                   | Inward Leakage<br>measured and<br>included in User<br>Instructions |
| Inhalation<br>resistance –<br>max pressure<br>drop   | ≤ 343 Pa                   | ≤ 70 Pa (at 30<br>L/min)<br>≤ 240 Pa (at 95<br>L/min)<br>≤ 500 Pa<br>(clogging) | ≤ 350 Pa                             | ≤ 70 Pa (at 30<br>L/min)<br>≤ 240 Pa (at 95<br>L/min)  | ≤ 70 Pa (at 30<br>L/min)<br>≤ 240 Pa (at 95<br>L/min)  | ≤ 70 Pa<br>(w/valve)<br>≤ 50 Pa (no<br>valve)                      |
| Flow rate  | 85 L/min                   | Varied – see<br>above   | 85 L/min                             | Varied – see<br>above                                  | Varied – see<br>above                                  | 40 L/min   |
| Exhalation<br>resistance -<br>max pressure<br>drop   | ≤ 245 Pa                   | ≤ 300 Pa  | ≤ 250 Pa                             | ≤ 120 Pa   | ≤ 300 Pa   | ≤ 70 Pa<br>(w/valve)<br>≤ 50 Pa (no<br>valve)                      |
| Flow rate  | 85 L/min                   | 160 L/min   | 85 L/min                             | 85 L/min   | 160 L/min  | 40 L/min   |
| Exhalation<br>valve leakage<br>requirement   | Leak rate ≤ 30<br>mL/min   | N/A   | Depressurization to 0 Pa ≥ 20<br>sec | Leak rate ≤ 30<br>mL/min                               | visual<br>inspection after<br>300 L /min for<br>30 sec | Depressurization to 0 Pa ≥ 15<br>sec                               |
| Force applied  | -245 Pa                    | N/A   | -1180 Pa                             | -250 Pa  | N/A  | -1,470 Pa  |
| CO <sub>2</sub> clearance<br>requirement   | N/A                        | ≤ 1%  | ≤ 1%                                 | ≤ 1%   | ≤ 1%   | ≤ 1%   |

\*Japan JMHLW-Notification 214 requires an Inward Leakage test rather than a TIL test.

Source: 3M Personal Safety Division, technical bulletin "Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes" January 2020, Revision 2 – <http://multimedia.3m.com>

PACKAGING



(a) = product



(b) = individual packing of (a)



(c) = 50 items of (b) bag



(d) = 20 bags of (c) – total 1000 units of (b)



# MANUFACTURER'S CERTIFICATES

Form QAT\_10-M04, version 00, effective since March 6th, 2020

**Certificate of Compliance**

No. 0P200316.TYUQ21  
Technical Construction File no. TPH820031222272

Certificate's Holder: Tangshan Yuchuang protective equipment Co., Ltd.  
No. 11 Geyensia street, Gaozhu District, Tangshan

Certification ECM Mark:  Type Approved

Product: Self-priming Filter Respirator for Particulate Matter Protection  
Model: (this certificate certifies only the product without its own specific model)

Verification to: Standard: EN 149:2001+A1:2009  
related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

**Remark:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

**CE**  Manufactured by Tangshan Yuchuang protective equipment Co., Ltd. for the CE mark. This document is issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01\_ECM rev.3 available at: [www.entecertmg.it](http://www.entecertmg.it)

Issuance date: 16 March 2020  
Expiry date: 15 March 2025

Reviewer: Technical expert Amanda Payne  
Approver: ECM Service Director Luca Badarri

**Ente Certificazione Macchine Srl**  
Via Ca' Bella, 243 - Loc. Castello di Serravalle - 40053 Valsamoggia (BO) - ITALY  
Tel: +39 051 7705141 Fax: +39 051 7705142 Email: [info@ente-certmg.it](mailto:info@ente-certmg.it) Website: [www.entecertmg.it](http://www.entecertmg.it)

No: XMT0202001253LY/PPE

唐山市防护用品有限公司

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## ***EC Declaration of conformity***

**Council Directive R 2016/425 (Regulation on Personal Protective Equipment)**

**TANGSHAN YUCHUANG PROTECTIVE EQUIPMENT CO.,LTD  
NO.44 GUYE SIDE STREET, GUYE DISTRICT, TANGSHAN  
CITY,HEBEI,CHINA**

唐山市防护用品有限公司

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Certify that the product described is in conformity with the Directive R.2016/425  
as amended

此资质仅用于出口海关

**Product Name:**

**Face Mask**

仅一次性使用

**Item No:**

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The product has been assessed by the application of the following standards:

其他用途一律无效

**EN 149:2001+A1:2009**

**Issue place and date**

唐山市防护用品有限公司

**Company stamp and Signature of authorized personnel**

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No: XMT0202001253LY/PPE

TANGSHAN YUCHUANG PROTECTIVE EQUIPMENT CO.,LTD

## CE Technical Documents

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# 此资质仅用于出口海关

Product name: Face Mask

Applied Directive : Regulation on Personal Protective Equipment (R 2016/425)

Document No.: XMT0202001253LY/PPE

Revision: V0

# 仅一次性使用

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# 其他用途一律无效

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|                                    |             |       |            |
|------------------------------------|-------------|-------|------------|
| Compiled by:<br>(Name/Title/Dept.) | Sadie       | Date: | 2020-03-23 |
| Reviewed by<br>(Name/Title/Dept.)  | 唐山市防护用品有限公司 | Date: | 2020-03-23 |
| Approved by:<br>(Name/Title/Dept.) | Amy         | Date: | 2020-03-23 |

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No: XMT0202001253LY/PPE

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|   |  |  |  |
|---|--|--|--|
| <b>Applicant</b>  | TANGSHAN YUCHUANG PROTECTIVE EQUIPMENT CO.,LTD                   |  |  |
| <b>Address</b>  | NO.44 GUYE SIDE STREET, GUYE DISTRICT, TANGSHAN CITY,HEBEI,CHINA |  |  |
| <b>Test Item Description</b>  |  |  |  |
| Product Name :  | Face Mask  |  |  |
| Model/Type Reference :  | KN95, YC 9501, JF9021V   |  |  |
| Standard :  | EN 149:2001+A1:2009  |  |  |
| <b>Test Case Verdicts</b>   |  |  |  |
| Test case does not apply to the test object :   | N(A.)  |  |  |
| Test item does meet the requirement :   | P(ass)   |  |  |
| Test item does not meet the requirement :   | F(ail)   |  |  |
| <b>General Remarks</b>  |  |  |  |
| <ul style="list-style-type: none"><li>• This report shall not be reproduced except in full without the written approval of the testing laboratory.</li><li>• The test results presented in this report relate only to the item tested.</li><li>• Clause numbers between brackets refer to clauses in EN 149:2001+A1:2009.</li><li>• "(see remark #)" refers to a remark appended to the report.</li><li>• "(see Annex #)" refers to an annex appended to the report.</li><li>• Throughout this report a point is used as the decimal separator.</li></ul> |  |  |  |

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## EN 149:2001+A1:2009

## Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking

|     |  |                     |   |
|-----|--|---------------------|---|
| 5   | Classification   |                     | - |
|     | Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices: FFP1, FFP2 and FFP3.  | FFP2                | P |
|     | The protection provided by an FFP2 - or FFP3 - device includes that provided by the device of lower class or classes.  | provided by an FFP2 | P |
| 6   | Designation  |                     | - |
|     | Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner:<br>Particle filtering half mask EN 149 year of publication, classification, option (where "D" is an option for a non re-useable particle filtering half mask and mandatory for re-useable particle filtering half mask).   |                     | P |
| 7   | Requirements   |                     | - |
| 7.1 | General  |                     | - |
|     | In all tests all test samples shall meet the requirements.   |                     | P |
| 7.2 | Nominal values and tolerances  |                     | - |
|     | Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of $\pm 5\%$ . Unless otherwise specified, the ambient temperature for testing shall be $(16 \pm 3)^\circ\text{C}$ , and the temperature limits shall be subject to an accuracy of $\pm 1^\circ\text{C}$ . | Accord              | P |
| 7.3 | Visual inspection  |                     | - |
|     | The visual inspection shall also include the marking and the information supplied by the manufacturer.   |                     | P |
| 7.4 | Packaging  |                     | - |
|     | Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.   |                     | P |
| 7.5 | Material   |                     | - |
|     | Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.   |                     | P |
| 7.6 | Cleaning and disinfecting  |                     | - |
|     | If the particle filtering half mask is designed to be re-useable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.  |                     | P |
| 7.7 | Practical performance  |                     | - |
|     | The particle filtering half mask shall undergo practical performance tests under realistic conditions.   |                     | P |



|             |   |                                   |   |
|-------------|---|-----------------------------------|---|
| 唐山市防护用品有限公司 | These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.                    | 唐山市防护用品有限公司                       | 唐 |
| 7.8         | Finish of parts   | -                                 |   |
|             | Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.   | P                                 |   |
| 7.9         | Leakage   | -                                 |   |
| 7.9.1       | Total inward leakage  | -                                 |   |
|             | The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. | indicated                         | P |
| 7.9.2       | Penetration of filter material  | -                                 |   |
| 唐山市防护用品有限公司 | The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1  | See Table 1                       | P |
| 7.10        | Compatibility with skin   | -                                 |   |
|             | Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.                            |                                   |   |
| 7.11        | Flammability  | -                                 |   |
|             | The material used shall not present a danger for the wearer and shall not be of highly flammable nature.  | P                                 |   |
| 7.12        | Carbon dioxide content of the inhalation air  | -                                 |   |
|             | The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 10 % (by volume).  | P                                 |   |
| 7.13        | Head harness  | -                                 |   |
| 唐山市防护用品有限公司 | The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.   | 唐山市防护用品有限公司                       | P |
| 7.14        | Field of vision   | -                                 |   |
|             | The field of vision is acceptable if determined so in practical performance tests.  | P                                 |   |
| 7.15        | Exhalation valve(s)   | -                                 |   |
|             | A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations   | P                                 |   |
| 7.16        | Breathing resistance  | -                                 |   |
|             | The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.   | meet the requirements of Table 2. |   |
| 唐山市防护用品有限公司 | Clogging  | 唐山市防护用品有限公司                       | 唐 |
| 7.17.1      | General   | -                                 |   |
|             | "For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory."   | P                                 |   |
| 7.17.2      | Breathing resistance  | -                                 |   |
| 7.17.2.1    | Valved particle filtering half masks  | -                                 |   |
|             | After clogging the inhalation resistances shall not exceed<br>FFP1: 4 mbar<br>FFP2: 5 mbar<br>FFP3: 7 mbar  | P                                 |   |

|        |   |                                   |   |  |
|--------|---|-----------------------------------|---|--|
| 7.17.2 | Valveless particle filtering half masks<br>After clogging the inhalation and exhalation resistances shall not exceed<br>FFP1: 3 mbar<br>FFP2: 4 mbar<br>FFP3: 5 mbar<br>at 95 l/min continuous flow.  | 唐山市防护用品有限公司                       | - |  |
| 7.17.3 | Penetration of filter material<br>All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment. | 唐山市防护用品有限公司                       | P |  |
| 7.18   | Demountable parts<br>All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.  | 唐山市防护用品有限公司                       | - |  |
| 8      | Testing   | 唐山市防护用品有限公司                       | P |  |
| 8.1    | General<br>If no special measuring devices and methods are specified, commonly used devices and methods shall be used.  | 唐山市防护用品有限公司                       | - |  |
| 8.2    | Visual inspection<br>The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests.   | 唐山市防护用品有限公司                       | - |  |
| 8.3    | Conditioning  | 唐山市防护用品有限公司                       | - |  |
| 8.3.1  | Simulated wearing treatment<br>Conditioning by simulated wearing treatment shall be carried out by the following process:   | 唐山市防护用品有限公司                       | P |  |
| 8.3.2  | Temperature conditioning<br>Expose the particle filtering half masks to the following thermal cycle:<br>a) for 24 h to a dry atmosphere of $(70 \pm 3)^\circ\text{C}$ ;<br>b) for 24 h to a temperature of $(-30 \pm 3)^\circ\text{C}$ ;                                      | 唐山市防护用品有限公司                       | - |  |
| 8.3.3  | Mechanical strength<br>Conditioning shall be done in accordance with EN 143.  | 唐山市防护用品有限公司                       | P |  |
| 8.3.4  | Flow conditioning<br>A total of 3 valved particle filtering half masks shall be tested, one as received and two temperature conditioned in accordance with 8.3.2.   | 唐山市防护用品有限公司                       | - |  |
| 8.4    | Practical performance<br>General<br>A total of 2 particle filtering half masks shall be tested: both as received.   | 唐山市防护用品有限公司                       | - |  |
| 8.4.2  | Walking test<br>The subjects wearing normal working clothes and wearing the particle filtering half mask shall walk at a regular rate of 6 km/h on a level course. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min. | 唐山市防护用品有限公司                       | P |  |
| 8.4.3  | Work simulation test<br>The particle filtering half mask shall be tested under conditions which can be expected during normal   | 唐山市防护用品有限公司                       | - |  |
|        |   | within a total working time of 20 | P |  |



|             |           |  |                           |    |
|-------------|-----------|--|---------------------------|----|
| 唐山市防护用品有限公司 | 8.5       | During this test the following activities shall be carried out in simulation of the practical use of the particle filtering half mask. The test shall be completed within a total working time of 20 min.  | 唐山市防护用品有限公司               | 唐L |
|             | 8.5       | Leakage  | -                         |    |
|             | 8.5.1     | General test procedure   | -                         |    |
|             | 8.5.1.1   | Total inward leakage   | -                         |    |
|             |           | A total of 10 test specimens shall be tested: 5 as received and 5 after temperature conditioning in accordance with 8.3.2.   | in accordance with 8.3.2. | P  |
|             | 8.5.1.2   | Test equipment   | -                         |    |
| 唐山市防护用品有限公司 |           | The test atmosphere shall preferably enter the top of the enclosure through a flow distributor, and be directed downwards over the head of the test subject at a minimum flow rate of 0.12 m/s. The concentration of the test agent inside the effective working volume shall be checked to be homogeneous. The flow rate should be measured close to the subject's head.  | 唐山市防护用品有限公司               | 唐L |
|             | 8.5.1.3   | Test procedure   | -                         |    |
|             |           | Ask the test subjects to read the manufacturer's fitting information and if more than one size of particle filtering half mask is manufactured, ask the test subject to select the size deemed by him to be the most appropriate. If necessary the test supervisor shall show the test subjects how to fit the particle filtering half mask correctly in accordance with the fitting information.  | P                         |    |
| 唐山市防护用品有限公司 | 8.5.2     | Method   | -                         | 唐L |
|             | 8.5.2.1   | Principle  | -                         |    |
|             |           | The subject wearing the particle filtering half mask under test walks on a treadmill over which is an enclosure  | -                         |    |
|             | 8.5.2.2   | Test equipment   | -                         |    |
|             | 8.5.2.2.1 | Aerosol generator  | -                         |    |
| 唐山市防护用品有限公司 |           | The NaCl aerosol shall be generated from a 2 % solution of reagent grade NaCl in distilled water. An atomizer equivalent to the type described should be used. This requires an air flow rate of 100 l/min at a pressure of 7 bar. The atomizer and its housing shall be fitted into a duct through which a constant flow of air is maintained. It may be necessary to heat or dehumidify the air in order to obtain complete drying of the aerosol particles. | 唐山市防护用品有限公司               | 唐L |
|             | 8.5.2.2.2 | Test agent   | -                         |    |
|             |           | The mean NaCl concentration within the enclosure shall be $(8 \pm 4) \text{ mg/m}^3$ and the variation throughout the effective working volume shall be not more than 10 %. The particle size distribution shall be 0.02 $\mu\text{m}$ to 2 $\mu\text{m}$ equivalent aerodynamic diameter with a mass median diameter of 0.6 $\mu\text{m}$ .   | P                         |    |
|             | 8.5.2.2.3 | Flame photometer   | -                         |    |
|             |           | A flame photometer shall be used to measure the  | P                         |    |



|             |  |             |    |
|-------------|--|-------------|----|
| 唐山市防护用品有限公司 | concentration of NaCl inside the particle filtering half mask. Essential performance characteristics for a suitable instrument are:<br>a) It should be a flame photometer specifically designed for the direct analysis of NaCl aerosol;<br>b) It should be capable of measuring concentrations of NaCl aerosol between 15 mg/m <sup>3</sup> and 5 ng/m <sup>3</sup> ;<br>c) The total aerosol sample required by the photometer should not be greater than 15 l/min;<br>d) The response time of the photometer, excluding the sampling system, should not be greater than 500 ms;<br>e) It is necessary to reduce the response to other elements, particularly carbon, the concentration of which will vary during the breathing cycle. This will be achieved by ensuring that the band pass width of the interference filter is not greater than 3 nm and that all necessary side band filters are included.   | 唐山市防护用品有限公司 | 康L |
| 唐山市防护用品有限公司 | 8.5.2.2.4 Sample selector<br>A system is required which will switch the sample to the photometer only during the inhalation phase of the respiratory cycle. During the exhalation phase clean air shall be fed to the photometer. The essential elements of such a system are:<br>a) An electrically operated valve with a response time of the order of 100 ms. The valve should have the minimum possible dead space compatible with straight-through, unrestricted flow when open;<br>b) A pressure sensor which is capable of detecting a minimum pressure change of approx 0.05 mbar and which can be connected to a probe inserted in the cavity of the particle filtering half mask. The sensor shall have an adjustable threshold and be capable of differential signaling when the threshold is crossed in either direction. The sensor shall work reliably when subjected to the accelerations produced by the head movements of the subject;<br>c) An interfacing system to actuate the valve in response to a signal from the pressure sensor;<br>d) timing device to record the proportion of the total respiratory cycle during which sampling took place. | 唐山市防护用品有限公司 | 康L |
| 唐山市防护用品有限公司 | 8.5.2.2.5 Sampling probe<br>The probe shall be fitted securely in a airtight manner to the particle filtering half mask as near as possible to the centre line of the particle filtering half mask. A multiple hole sampling probe is strongly recommended.  | 唐山市防护用品有限公司 | 康L |
| 唐山市防护用品有限公司 | 8.5.2.2.6 Sample pump<br>If no pump is incorporated into the photometer an adjustable flow pump is used to withdraw an air sample from the particle filtering half mask under test. This pump is so adjusted as to withdraw a constant flow of 1 l/min from the sample probe. Dependent on the type of photometer it may be  | 唐山市防护用品有限公司 | 康L |

Comply with the requirements

唐山市防护用品有限公司



P

|             |   |             |   |
|-------------|---|-------------|---|
| 唐山市防护用品有限公司 | necessary to dilute the sample with clean air.  | 唐山市防护用品有限公司 | 唐 |
| 8.5.2.2.7   | Sampling of enclosure concentration<br>The enclosure aerosol concentration is monitored during the tests using a separate sampling system, to avoid contamination of the particle filtering half mask sampling lines. It is preferable to use a separate flame photometer for this purpose.                       | -           |   |
|             |   | P           |   |
| 8.5.2.2.8   | Pressure detection probe<br>A second probe is fitted near to the sample probe and is connected to the pressure sensor.  | -           |   |
|             |   | P           |   |
| 8.5.2.3     | Expression of results<br>The leakage P shall be calculated from measurements made over the last 100 s of each of the exercise periods to avoid carry over of results from one exercise to the other.  | -           |   |
|             |   | P           |   |
| 唐山市防护用品有限公司 | $P_{0.05} = \frac{C_1}{C_2} \times \frac{(t_{IN}/t_{EX})}{t_{IN}} \times 100$   | 唐山市防护用品有限公司 | 唐 |
|             | where<br>C1 is the challenge concentration<br>C2 is the measured mean concentration in the breathing zone of the test subject<br>tIN is the total duration of inhalation<br>tEX is the total duration of exhalation   | -           |   |
| 8.6         | Flammability<br>A total of four particle filtering half masks shall be tested: two in the state as received and two after temperature conditioning in accordance with 8.3.2.  | -           |   |
|             |   | P           |   |
| 8.7         | Carbon dioxide content of the inhalation air<br>A total of 3 particle filtering half masks shall be tested: all 3 as received.  | -           |   |
|             |   | P           |   |
| 8.8         | Strength of attachment of exhalation valve housing<br>A total of three particle filtering half masks shall be tested: one as received, one temperature conditioned in accordance with 8.3.2 and one after the test described for mechanical strength in EN 143  | -           |   |
| 8.9         | Breathing Resistance  | -           |   |
| 8.9.1       | Test samples and fixture  | -           |   |
| 8.9.1.1     | Valveless particle filtering half masks<br>A total of 9 "valveless particle filtering" half masks shall be tested:<br>3 as received, 3 after temperature conditioning in accordance with 8.3.2 and 3 after the test for simulated wearing in accordance with 8.3.1  | -           |   |
| 8.9.1.2     | Valved particle filtering half masks<br>A total of 12 valved particle filtering half masks shall be tested: 3 as received, 3 after temperature conditioning in accordance with 8.3.2, 3 after the test for simulated wearing in accordance with 8.3.1 and 3 after the flow conditioning in accordance with 8.3.4. | P           |   |
| 8.9.2       | Exhalation resistance<br>Seal the particle filtering half mask on the Sheffield dummy head. Measure the exhalation resistance at the opening for mouth of the dummy head using the adapter shown in Figure 6 and a breathing machine  | -           |   |
|             |   | P           |   |



|             |   |             |      |   |
|-------------|---|-------------|------|---|
| 唐山市防护用品有限公司 | adjusted to 25 cycles/min and 20 L/min or a continuous flow 160 l/min. Use a suitable pressure transducer.  | 唐山市防护用品有限公司 |      | 唐 |
| 8.9.3       | Inhalation resistance   |             | -    |   |
|             | Test the inhalation resistance at 30 l/min and 95 l/min continuous flow.  |             | P    |   |
| 8.10        | Clogging  |             | -    |   |
| 8.10.1      | Principle   |             | -    |   |
|             | The test aerosol shall be dolomite. A total of 3 particle filtering half masks shall be tested: 1 as received and 2 after temperature conditioning in accordance with 8.3.2.  |             | P    |   |
| 8.10.2      | Test equipment  |             | -    |   |
| 唐山市防护用品有限公司 | A scheme of a typical apparatus is given in Figure 10. The working area of the test chamber has a suggested square section of 650 mm × 650 mm.  | 唐山市防护用品有限公司 | P    | 唐 |
| 8.10.3      | Test conditions   |             | -    |   |
|             | Dust: DRB 4/15 dolomite.<br>The size distribution of dolomite dust is given in Table 3.   | 唐山市防护用品有限公司 | P    | 唐 |
| 8.10.4      | Test procedure  |             | -    |   |
|             | Convey dust from the distributor to the dust chamber where it is dispersed into the air stream of 60 m <sup>3</sup> /h.   |             | P    |   |
| 8.10.5      | Assessment of clogging  |             | -    |   |
|             | Following the exposure, measure the breathing resistance of the particle filtering half mask using clean air. Then measure the filter penetration in accordance with 8.11.  |             | P    |   |
| 唐山市防护用品有限公司 | Penetration of filter materials   | 唐山市防护用品有限公司 | -    | 唐 |
|             | The device shall be mounted in a leaktight manner on a suitable adapter and subjected to the test(s), ensuring that components of the device that could affect filter penetration values such as valves and harness attachment points are exposed to the challenge aerosol. |             |      |   |
| 9           | Marking   |             | P    |   |
| 9.1         | Packaging   |             | -    |   |
|             | The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.   |             |      |   |
| 9.1.1       | The name, trademark or other means of identification of the manufacturer or supplier  | 唐山市防护用品有限公司 | P    | 唐 |
| 9.1.2       | Type-identifying marking.   |             |      |   |
| 9.1.3       | Classification  |             |      |   |
|             | The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then:<br>"NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or<br>"R" if the particle filtering half mask is re-usable. Example: FFP2 R D."          | 唐山市防护用品有限公司 | FFP2 | P |
| 9.1.4       | The number and year of publication of this European Standard.   |             | -    |   |
| 9.1.5       | At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in  |             | P    |   |



## A4 / 07.17



Production Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

**Manufacturer**

TO BE DISCLOSED

**Facility(ies):**

**Product Category(ies):**

**Gauze Pads, Disposable Shoe Covers,  
Gauze Rolls, Disposable Sterile Surgical  
Masks, Disposable Sterile Surgical Caps,  
Disposable Sterile Surgical Gown,  
Disposable Sterile Surgical Drapes,  
Disposable Sterile Bed Sheet, Disposable  
Sterile Pad, Disposable Sterile Towel**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH18101608

Valid from: 2019-04-26  
Valid until: 2022-03-12

Date, 2019-04-26

S. Pennit

Stefan Preiß

Page 1 of 1

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®



## Certificate

No. Q6 095416 0009 Rev. 01

Holder of Certificate: **TO BE DISCLOSED**

Certification Mark:



Scope of Certificate:

Production and Distribution of Surgical Bandages, Disposable PE Film Gloves, Medical Wraps, Disposable Suction Catheters, Disposable Rubber Surgical Gloves, Nebulizer Masks, Connecting Tubes with Yankauer Handle, Humidification Bottle, Anesthesia and Breathing Circuit, Disposable Sterile Infusion Sets, Three-way Stopcocks, Disposable Surgical Blades, Disposable Sterile Blood Lancets, Oxygen Masks with Reservoir Bags, Gauze Pads, Sterile Vaginal Dilators for Single Use, Disposable Syringes, X-Ray Detectable Gauze Pads, Disposable Shoe Covers, Gauze Rolls, Disposable Sterile Surgical Masks, Disposable Sterile Surgical Caps, Disposable Sterile Surgical Gown, Disposable Sterile Surgical Drapes, Disposable Sterile Bed Sheets, Disposable Sterile Pads, Disposable Sterile Towel, I.V. Catheters, Disposable Endotracheal Tubes, Disposable Urethral Catheters, Disposable Nasal Oxygen Cannulas, Disposable Stomach Tubes, Laryngeal Masks, Anesthesia Masks and Oxygen Masks

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19108609  
 Valid from: 2020-03-14  
 Valid until: 2023-03-13

Date, 2020-02-11

Christoph Dicks  
 Head of Certification/Notified Body



## Certificate

No. Q6 095416 0009 Rev. 01

**Applied Standard(s):** EN ISO 13485:2016  
 Medical devices - Quality management systems -  
 Requirements for regulatory purposes  
 (ISO 13485:2016)  
 DIN EN ISO 13485:2016

**Facility(ies):** TO BE DISCLOSED