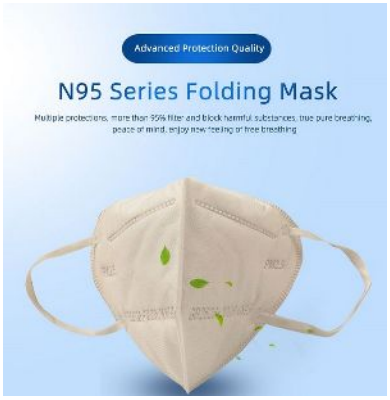
Personal protection equipment

KN95 PM2.5

rev. 9



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 Tech construction file n. TPHB20031222272 EN149:2001+A1:2009 | CE Directive R2016/425
	Composition	4 layers: 40 gsm non-vowen + 50 gsm melt-blown fabric + 60 gsm cotton + 20 gsm non-vowen
	Packing	Individually packed units | 50 units per bag | 20 bags or 1000 units per carton | 9 kg per carton 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

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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/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS (Japan JMHLW-Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and 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 leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurization to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa
CO_2 clearance 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 bullettin "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

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Form QAT_10-M04, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 0P200316.TYUQ21

Technical Construction File no. TPHB20031222272

Certificate's Holder: Tangshan Yuchuang protective equipment Co., Ltd.
No. 44 Qiaoxiao street, Guye District, Tangshan City, Hebei.

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 — manufacturer must affix the CE marking. 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.entecerma.it

Issuance date: 16 March 2020

Expiry date: 15 March 2025

Reviewer	Approver
Technical expert	ECM Service Director
Amanda Payne	Luca Bedonni

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
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No: XMT0202001253LY/PPE

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

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

Product Name:

Face Mask

Item No:

KN95, YC 9501, JF9021V

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

EN 149:2001+A1:2009

Issue place and date

Company stamp and Signature of authorized personnel

No: XMT0202001253LY/PPE

TANGSHAN YUCHUANG PROTECTIVE EQUIPMENT CO.,LTD

CE Technical Documents

Product name: Face Mask

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

Document No.: XMT0202001253LY/PPE

Revision: V0

Compiled by: (Name/Title/Dept.)	Sadie	Date:	2020. 03. 23
Reviewed by (Name/Title/Dept.)		Date:	2020. 03. 23
Approved by: (Name/Title/Dept.)		Date	2020. 03. 23

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

Test Item Description	
Product Name :	Face Mask
Model/Type Reference :	KN95, YC 9501, JF9021V
Standard :	EN 149:2001+A1:2009

Test Case Verdicts	
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)

General Remarks

- This report shall not be reproduced except in full without the written approval of the testing laboratory.
- The test results presented in this report relate only to the item tested.
- Clause numbers between brackets refer to clauses in EN 149:2001+A1:2009.
- "(see remark #)"refers to a remark appended to the report.
- "(see Annex #)"refers to an annex appended to the report.
- Throughout this report a point is used as the decimal separator.

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:		P
	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 ± 5 %. Unless otherwise specified, the ambient temperature for testing shall be (15 - 35) °C and the temperature limits shall be subject to an accuracy of ± 3 °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-usable, 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

	These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.		
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		-
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	See Table 1	P
7.10	Skin 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.		P
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 1,0 % (by volume).		P
7.13	Head harness		-
	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.		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.	P
7.17	Clogging		-
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 FFP1: 4 mbar FFP2: 5 mbar FFP3: 7 mbar		P

7.17.2	Valveless particle filtering half masks		-
	After clogging the inhalation and exhalation resistances shall not exceed FFP1: 3 mbar FFP2: 4 mbar FFP3: 5 mbar at 95 l/min continuous flow.		P
7.17.3	Penetration of filter material 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.		P
7.18	Demountable parts		-
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.		P
8	Testing		
8.1	General If no special measuring devices and methods are specified, commonly used devices and methods shall be used.		P
8.2	Visual inspection		-
	The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests.		P
8.3	Conditioning		-
8.3.1	Simulated wearing treatment		-
	Conditioning by simulated wearing treatment shall be carried out by the following process:		P
8.3.2	Temperature conditioning		-
	Expose the particle filtering half masks to the following thermal cycle: a) for 24 h to a dry atmosphere of (70 ± 3) °C; b) for 24 h to a temperature of (-30 ± 3) °C;		P
8.3.3	Mechanical strength		-
	Conditioning shall be done in accordance with EN 143.		P
8.3.4	Flow conditioning		-
	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.	in accordance with 8.3.2.	P
8.4	Practical performance		
8.4.1	General		-
	A total of 2 particle filtering half masks shall be tested: both as received.		P
8.4.2	Walking test		-
	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.		P
8.4.3	Work simulation test		-
	The particle filtering half mask shall be tested under conditions which can be expected during normal	within a total working time of 20	P

	use. 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.		
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		-
	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.		P
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
8.5.2	Method		-
8.5.2.1	Principle		-
	The subject wearing the particle filtering half mask under test walks on a treadmill over which is an enclosure.		P
8.5.2.2	Test equipment		-
8.5.2.2.1	Aerosol generator		-
	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.		P
8.5.2.2.2	Test agent		-
	The mean NaCl concentration within the enclosure shall be (8 ± 4) mg/m3 and the variation throughout the effective working volume shall be not more than 10 %. The particle size distribution shall be 0,02 μm to 2 μm equivalent aerodynamic diameter with a mass median diameter of 0,6 μm.		P
8.5.2.2.3	Flame photometer		-
	A flame photometer shall be used to measure the		P

	concentration of NaCl inside the particle filtering half mask. Essential performance characteristics for a suitable instrument are: a) It should be a flame photometer specifically designed for the direct analysis of NaCl aerosol; b) It should be capable of measuring concentrations of NaCl aerosol between 15 mg/m3 and 5 ng/m3; c) The total aerosol sample required by the photometer should not be greater than 15 l/min; d) The response time of the photometer, excluding the sampling system, should not be greater than 500 ms; 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 no greater than 3 nm and that all necessary side band filters are included.	Comply with the requirements	
8.5.2.2.4	Sample selector 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: 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; 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; c) An interfacing system to actuate the valve in response to a signal from the pressure sensor; d) timing device to record the proportion of the total respiratory cycle during which sampling took place.		P
8.5.2.2.5	Sampling probe The probe shall be fitted securely in an 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.		P
8.5.2.2.6	Sample pump 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		- P

	necessary to dilute the sample with clean air.		
8.5.2.2.7	Sampling of enclosure concentration		-
	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		-
	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		-
	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
	$P(\%) = \frac{C_2}{C_1} \times \frac{t_{IN}}{t_{EX}} \times 100$ where C1 is the challenge concentration C2 is the measured mean concentration in the breathing zone of the test subject tIN is the total duration of inhalation tEX is the total duration of exhalation		-
8.6	Flammability		-
	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		-
	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		-
	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		P
8.9	Breathing Resistance		-
8.9.1	Test samples and fixture		-
8.9.1.1	Valveless particle filtering half masks		-
	A total of 9 "valveless particle filtering" half masks shall be tested: 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		P
8.9.1.2	Valved particle filtering half masks		-
	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 8.3.1and 3 after the flow conditioning in accordance with 8.3.4.		P
8.9.2	Exhalation resistance		-
	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

	adjusted to 25 cycles/min and 2 l stroke or a continous flow 160 l/min. Use a suitable pressure transducer.		
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		-
	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.		P
8.10.3	Test conditions		-
	Dust: DRB 4/15 dolomite		
	The size distribution of dolomite dust is given in Table 3.	given in Table 3.	P
8.10.4	Test procedure		-
	Convey dust from the distributor to the dust chamber where it is dispersed into the air stream of 60 m3/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.	in accordance with 8.11.	P
8.11	Penetration of filter material		-
	The device shall be mounted in a leaktight manner on a suitable adaptor 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.		P
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.		P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.		-
9.1.2	Type-identifying marking.		-
9.1.3	Classification The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D."	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

DISTRIBUTOR'S CERTIFICATES

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

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)

No. G2S 095912 0009 Rev. 00

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

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®

A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

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

A4 / 07.17

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

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

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

.

A4 / 07.17

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