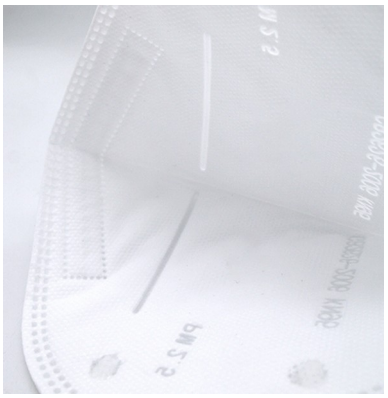
greensley medical

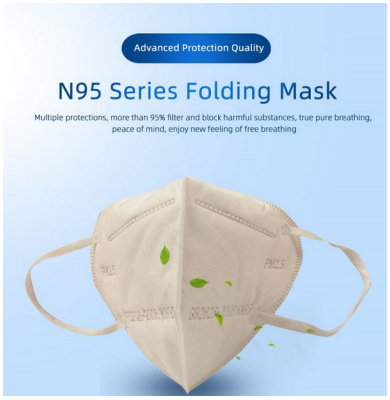
Personal protection equipment

KN95 PM2.5

disposable face mask

rev. 5





Code	Description	
KN95-CE	KN95 disposable face mask, CE mark	Individually packed units 50 units per bag 20 bags / 1000 units per carton 9 kg / 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 equivalency	N95 (NIOSH-42C FR84) equivalent to FFP2 (EN 149-2001) – see below

E&OE

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“greensley medical” is the medical products division of greensley limited
https://medical.greensley.eu | 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/ 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

<table>
<tr>
<td> 

(a) = product</td>
<td> 
(b) = individual packing of (a)</td>
</tr>
<tr>
<td> 
(c) = 50 items of (b) bag</td>
<td> 
(d) = 20 bags of (c) – total 1000 units of (b)</td>
</tr>
</table>

TEST REPORT

Testing Report

NO. 200217 CD/QR-8.2.4-03

Product Name	Medical Surgical Mask		**Specification**	Ear Loop	
Batch Number	200202		**Sterilization Date**	/	
Testing Department	Quality Control Department		**Testing Quantity**	80 PCS	
Sample Status	Intact		**Testing Time**	Feb. 3, 2020-Feb. 17, 2020	
Testing Standard	EN ISO 13485:2016+MDD Annex V				
Testing Item	**Item No.**	**Requirements**		**Result**	**Conclusion**
Appearance	2.1	The mask's appearance should be clean, unbroken, without any damage or stains.		Complied	Passed
Size	2.2	The mask must cover the wearer's nose, mouth and under jaw when it is put on. The size should meet the requirements of the stipulated size and permissible deviation(Length: 17.5cm±5%, width: 17cm±5%).		Length: 17.5cm Width: 17cm	Passed
Nasal Splint	2.3.1	The mask must be equipped with nasal splint, which is made of malleable material.		Complied	Passed
	2.3.2	The length of the nasal splint should be no less than 8.0cm		Minimum: 10.9cm	Passed
Mask Strip	2.4.1	The mask strip should be convenient when wearing.		Complied	Passed
	2.4.2	The breaking power between each mask strip and the connection point should be no less than 10N.		Complied	Passed
The penetration of Synthetic Blood	2.5	Spraying 2ml synthetic blood to the outer side of the mask with 16.0kpa(120mmHg) pressure, the inner side of the mask cannot be penetrated.		Complied	Passed
Filtration Rate of Bacterial	2.6.1	The filtration rate of bacterial should no less than 95%.		98%	Passed
Filtration Rate of Particle	2.6.2	The filtration rate of non-oily particles should be no less than 30%		Minimum:71%	Passed
Pressure Difference	2.7	The pressure difference △P between the two sides when they are in gas exchange situation should be no more than 49Pa		35Pa	Passed
Flame Retardation	2.8	The material of mask should be flame retardant. The combustion should continue less than 5s when the mask is away from the fire.		Complied	Passed
Testing Result: Passed					

检测人：

复核人：

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

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

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

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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

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DAkkS
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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

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