

Personal protection equipment
KN95 PM2.5
disposable face mask

rev. 2



Code	Description	Logistics
KN95	KN95 disposable face mask, CE mark	1000 pcs / carton - 9 kg / carton - 68*32*61 cm / carton

E&OE

greensley limited

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"greensley medical" is the medical products division of greensley limited

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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 ΔP 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:

郭世瑾

复核人:

高五红



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

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