

3 PLY CIVIL DISPOSABLE FACE MASK

DESCRIPTION:

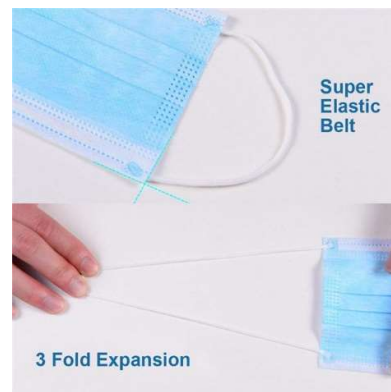
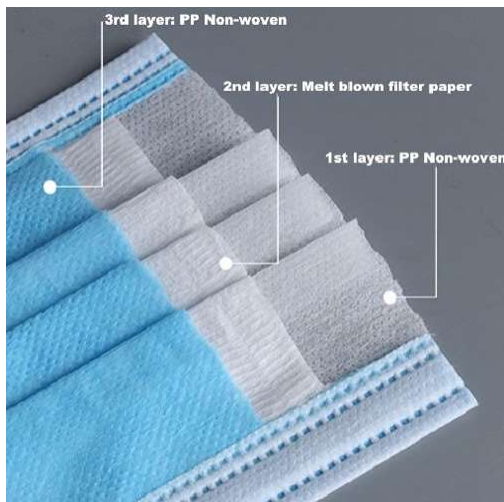
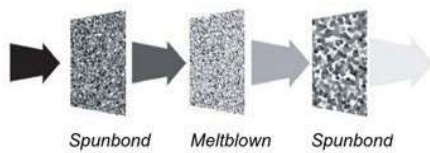
Material: PP nonwoven + Melt blown Filter

Unit size: 17.5X9.5cm

Features: Earloop, breathable and comfortable, low breathing resistance, fresh and clean fabric-like smell, fluid resistant, anti-bacterial

Standard: GB15979-2002

Manufacturer: **KRECO**



Components:

1st layer : Polypropylene Spunbond nonwoven

2nd layer : Meltblown Nonwoven

3rd layer : Polypropylene Spunbond nonwoven

Nose strip : PE wire (Metal Free)

Ear-Loop : Flat elastic or round elastic (latex free)

Very important note:

It is a civil mask, KRECO medical registration no. #:20200118.

Package:

50 pcs / box

50 boxes / carton

2000 pcs / carton,

Carton size: 55x45x42cm

Gross Weight: 11 kgs/carton

Production capacity:400k per day



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Certification:

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ ЗЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-85-244, 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 066 0008 Rev. 00

Manufacturer	Medical Health Products Co., Ltd.
	PEOPLE'S REPUBLIC OF CHINA
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffelstraße 80, 20537 Hamburg, GERMANY
Product Category(ies):	Surgical Drape, Surgical Gown, Sterile Surgical Kit, Face Mask.

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.: SH1 EXT01
Valid from: 2019-01-23
Valid until: 2024-01-22

Date, 2018-11-29

S. Preiß
Stefan Preiß

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



CERTIFICATE

No. Q6 17 09 007

Holder of Certificate: Medical Health Products Co., Ltd.

PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Medical Health Products Co., Ltd.
 PEOPLE'S REPUBLIC OF CHINA



Certification Mark:



Scope of Certificate: Production and Distribution of Surgical Drape, Dental Apron for Hospital Usage, Surgical Gown, Sterile Surgical Kit, Face Mask

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

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.: BH1 0

Valid from: 2018-01-01
Valid until: 2020-12-31



Date: 2017-12-05

Stefan Preiß
 Stefan Preiß

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