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

Certificate of Compliance

No. 0H200313.NYMUU26

Test Report no. XMT0201901520S/PPE

Certificate's Holder:	Nanjing Yaoke Medical Equipment Co., Ltd. Floor 1, Building C5, No.9, Kechuang Avenue, Zhongshan Science and Technology Park, Jiangbei New District, Nanjing
Certification ECM Mark:	ENTE CERTIFICAZIONE MACCHINE – European Conformity – SAFETY COMPLIANCE MARK – Type Approved
Product:	Disposable protective mask
Model(s):	17.5*9
Verification to:	Standard: EN 149:2001+A1:2009 related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it
This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:

CE

We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is Responsible to start the CE *Marking Certification Procedure* through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the CE Mark on the product(s).

Date of issue 14 March 2020

Expiry date 12 March 2025

Service Manager
Luca Bedonni

Deputy Manager
Amanda Payne

Ente Certificazione Macchine Srl
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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 068194 0008 Rev. 00

Manufacturer	**Zhangjiagang Zhiyi Medical Health Products Co., Ltd.** Renmin Road, Leyu Town 215622 Zhangjiagang City, Jiangsu Province PEOPLE'S REPUBLIC OF CHINA
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 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.:	SH18524EXT01
Valid from:	2019-01-23
Valid until:	2024-01-22

Date, 2018-11-29

I. Preiß

Stefan Preiß

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

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

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Facility(ies):

Zhangjiagang Zhiyi Medical Health Products Co., Ltd.
Renmin Road, Leyu Town, 215622 Zhangjiagang City,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

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