Review Report –审查报告–검토 보고서– Rapport d'Evaluation

CE Documentation Review

No. 4L200407.ZGNT016

Holder: New Material

400 Meters East of Xiangang Toll Station, Xianer Village, Xiangang Town, Gaoyao District, Zhaoqing City (No.2 Workshop of Xianer Village Committee), China

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable Medical Mask (Not Sterile)

Model(s): GL-02

Classification: Class I (Not Sterile) (accordingly to the Manufacturer's declaration)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices.
Technical documentation identified with the no. CTL2003209032-S.
The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been 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

Date of issue 07 April 2020
Approver
ECM Service Director
Luca Bedonni

Expiry date 06 April 2025

Technical Expert
Amanda Fayne

SHT-LAB

CERTIFICATION OF REGISTRATION

2020

SHT2003030FD

This certifies that:

Was registered with US Food and Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807, by Shenzhen SHT Testing Technology Co., Ltd.

Owner / Operator Number:	**10065080**
Device Listing #:	**See Annex**
Expiration Date:	**Dec. 31, 2020**

SHT will confirm that such registration remains effective upon request and presentation of this certificate until the and of the calendar year stated above, unless said registration is terminated after issuance of this certificate.

SHT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, SHT is not affiliated with the U.S. Food and Drug Administration.

Mar. 28, 2020
(Date)

Ryan MA
Lab Supervisor

Shenzhen SHT Testing Technology Co., Ltd.
Tel: 0755-23318846 Fax: 0755-23318846 http://www.sht-lab.com

SHT-LAB

Annex to Device Listing #:

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Filtering Facepiece Respirator, Disposable medical mask	KHA	1	D380623	Manufacturer

Mar. 28, 2020
(Date)

Ryan MA
Lab Supervisor

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