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

CE Documentation Review

No. 0H200314.XDHUD43

Holder: Shenzhen Gelaimei Electronics (Threestars) Co., Ltd.

Room 202, No.2 Building, East(133) of Jiuxiangling Industry Zone, Xili, Nanshan District, Shenzhen, China.

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable Medical Mask **(no sterile)**

Model(s): Black, pink, white, blue, green

Classification: Class I (no sterile)
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Test Report identified with the no. **XMT0201901550S/MDD**.
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

Issuance date: 14 March 2020

Expiry date: 13 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

Ente Certificazione Macchine
Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy
☎ +39.0516705141 🖷 +39.0516705156 ✉ info@entecerma.it 🌐 www.entecerma.it

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the council directive 93/42/EEC, SUNGO performed all notification duties and responsibilities as the European authorized representative of:

Applicant:	Jiangsu Eyoung Medical Devices Co.,Ltd
Address:	NO.1 Dongtang Road, Zhenglu Town, Tianning County, Changzhou City, Jiangsu Province,China

The Manufacturer has provided SUNGO with all the appropriate declarations according to the 93/42/EEC Directive requirements including the EC Declaration of Conformity confirming that his medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

Product(s):	Medical Face Mask
Type(s):	Non-sterile, ear loop, 17.5x9.5cm
Product Classification:	Class I

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

The notification of aforementioned device has been completed by the European Representative in United Kingdom. The UK Competent Authority is notified of the manufacturer's medical devices and has allocated registration. MHRA Registration number is CA017437.

SUNGO

Executive Director

Sungo global service CERTIFIED

Issued: Mar. 30 2020
Cert. No.: EU228518
Expiration Date: Mar. 29 2025

This is not a CE mark and is only provided as a template for informational purpose.

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