ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

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: [redacted]

Address: [redacted]

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

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

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60132306 0001

Report No.: 15096329 002

Manufacturer:

[redacted]

China

Products: Medical Devices

(see attachment for products included)

Expiry Date: 2023-09-10

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Notified Body

Effective Date: 2018-09-11

Date: 2018-09-11

K. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60132306 0001
Report No.: 15096329 002

Manufacturer:

[redacted]
China

Products:

- Syringes for Single Use
- Disposable Hypodermic Needles

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Infusion Spikes
- Face masks
- Oral syringes(with or without Adaptors)

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2018-09-11

X. Ren