CE

EC Declaration of Conformity

Manufacturer

Manufacturer:XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
Address: 4th Floor,No.1 Building,No.6 Ji'an Road,Tong'an District,Xiamen,Fujian,China

EC Representative

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable Surgical Mask
UMDNS-Code: 12447

Type: 17.5cm×9.5cm,14.5cm×9.5cm,12cm×8.5cm

Classification:The medical device has been assigned to class I rule1 according to Annex VIII of the Medical Device Regulation(EU 2017/745).

Conformity Assessment Route:Annex II+III

We confirm our product meet the requirement of Medical Device Regulation and the following harmonized standards.

EN ISO13485:2016
EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2008+A1:2013
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013
IEC 62366-1:2015
EN 14683:2019+AC:2019

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD 厦门美润医疗科技有限公司 单证专用章

April 21st, 2020
Date

Legally binding signature, Function

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

Sungo
global service

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:	Xiamen Probtain Medical Technology Co.,Ltd
Address:	4th Floor, No.1 Building, No.6 Ji'an Road, Tong'an District, Xiamen, Fujian 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 the medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

Product(s):	Disposable Medical Face Mask
Type(s):	N/A
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 Netherlands. The Netherlands Competent Authority is notified of the manufacturer's medical devices and has allocated registration. NOTIS number is CIBG-20200672.

Executive Director

Issued: Apr. 03 2020
Cert. No.: EU318518
Expiration Date: Apr. 02 2025