



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

April 21st, 2020

Date



Legally binding signature, Function