Declaration of Conformity

EC Declaration of Conformity

Manufacturer: Topgene & Osmunda Medical Device Co., Ltd.

Address: 64 Shuanglong Road, Huashan Town, Huadu District, Guangzhou, 510880, China

EU Authorised Representative:

Company: Osmunda Medical Technology Service GmbH

Address: Von Oppen-Weg 15, 14476 Potsdam, Germany

DIMDI code: DE/0000047267

Product name: Surgical face mask

UMDN code: 12-458

Classification: Class I

Rule: According to Rule 1, Annex VIII, Chapter III of (EU) MDR 2017/745

Conformity assessment route: ANNEX II + ANNEX III + Article 19 of (EU) MDR 2017/745

Intended use: Surgical face mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. The face mask is single use, provided non-sterile.

We hereby declare that the above mentioned product meets the provision of the Medical Device Regulation (EU) MDR 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

CE

Standard Applied:

EN ISO 13485:2016	EN ISO 14971:2012	EN 14683:2019 +AC: 2019	BS EN ISO 15223-1:2016
EN ISO 10993-1:2009/AC:2010	EN ISO 10993-5:2009	ISO 10993-10:2010	EN 1041:2008

Place, Date of Issue:

Guangzhou, 13th April 2020

Represented by Legal Representative:

Name: 田晓亮

Function: General Manager

Signature:

The signature is signed on behalf of Topgene & Osmunda Medical Device Co., Ltd.

Unauthorized use is prohibited