

EC Declaration of Conformity

Manufacturer: Jiande Chaomei Daily Chemicals Co.,Ltd.

Address: Shangshan village, Yangcunqiao town, Jiande city, Zhejiang province, China

EU Authorized Representative:

Company: Osmunda Medical Technology Service GmbH

Address: Treskowallee 108, 10318 Berlin, Germany

SRN: DE-AR-000009285

Product name: Surgical Face Mask

Model: F-Y1-B, F-Y1-C, F-Y3-D, F-Y3-H

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

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.



Standard Applied:

EN ISO 13485:2016	EN ISO 14971:2019	EN 14683:2019 +AC: 2019	EN ISO 15223-1:2021
EN ISO 10993-1:2020	EN ISO 10993-5:2009	ISO 10993-10:2021	EN 1041:2008+A1:2013

Place, Date of Issue:

Jiande, 05th August 2022

Represented by Deputy general manager:

Name: Liping Zhu

Function: Deputy general manager

Signature:

The signature is signed on behalf of

Jiande Chaomei Daily Chemicals Co.,Ltd.