

Declaration of Conformity

Manufacturer:

Name: Medwell Medical Products Co., Ltd.

Add: NO.999 Xue Song road, Fenglin town, Dean county, 330400 Jiujiang City, Jiangxi Province, People's Republic of China

European Representative:

Name: MedPath GmbH

Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Tel: +49(0)89 189174474 Fax: +49(0)89 5485 8884

Product Name: Surgical Mask (Type II ,Type IIR)

Types/Size: Type: Earloop mask, Rope—lined mask, Headloop mask

Size: 14.5cm x 9.5cm, 17cm x 9.5cm, 17.5cm x 9.5cm, 21cm x9.5cm

The UMDNS code: 12-458

Product performance meets the requirements of EN14683-2019

Classification and relevant Rule of MDD: I , rule 1

Product Certification Conformity Assessment Route: Annex VII

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Start of CE Marking: 2020.04.25

Place, Date of Issue: Jiujiang, China, 2020.06.10

Signature of issue person:

Position: General

Manager

