



江苏麦普拉卫生材料有限公司
JIANGSU MEDPLUS NON-WOVEN MANUFACTURER CO.,LTD.
Address: NO.217 EAST WENCHENG ROAD, ECONOMIC DEVELOPMENT ZONE, SIYANG,
JIANGSU,223700.CHINA
TEL:+86-514-86440123; FAX:+86-21-51861120

Declaration of Conformity

Manufacturer:

Jiangsu Medplus Non-woven Manufacturer Co., Ltd.

Address: NO.217 EAST WENCHENG ROAD, ECONOMIC DEVELOPMENT ZONE, SIYANG,
JIANGSU, 223700.CHINA

Tel: +86-514-86440123 Fax: 0086-21-51861120

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Standard Procedure Mask

Classification: Class I, Rule 1, Annex IX, MDD 93/42/EEC

UMDNS Code: 12458

Type: Type IIR

Specification: Elastic Earloop

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, the standards of EN ISO 13485:2016 and EN 14683:2019. All supporting documentations are retained under the promises of the manufacturer: Jiangsu Medplus Non-woven Manufacturer Co., Ltd. is exclusively responsible for Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 5 Sept 2007 concerning medical devices.

Start of CE Marking: 02/07/2020

Place, Date of Issue:

Siyang, Jiangsu

02/15/2020

General Manager

(Name and signature or equivalent
Marking of authorized person)

