



Declaración de Conformidad

Jiangxi Health Medical Technology Co., LTD

Disposable Medical Surgical Face Mask CE TF

01 Declaration of Conformity

Manufacturer: Name: Jiangxi Health Medical Technology Co., LTD
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Jiangxi,China
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European Representative: Name: ZOUSTECH S.L.
Add: Pso. Castellana,141-Planta 19, 28046-Madrid, Spain
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Product Name: Disposable Medical Surgical Face Mask
Object of the declaration: Model: H&S-MM-MI
Size: 14.5cm x 9cm, 17.5cm x 9.5cm, 12cm x 7.5cm
UMDNS Code: 12-458
Classification (MDD, Annex IX): I , rule 1
Conformity Assessment Route: Annex VII

We herewith declare in sole responsibility 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 modified with the Directive 2007/47/EC

Applicable standards by EU

ENISO13485:2016	EN 14683:2019+AC:2019	ISO14971:2019
ISO10993-1:2018	ENISO10993-5:2009	ISO10993-10:2010
ENISO 15223-1:2016	EN1041:2008/A1:2013	

Place of Issue: Nanchang, Jiangxi, China

Date of Issue: 2020.06.28

Signature:



Mr. LEO

Position: General Manager