

Mascarilla Quirúrgica / Quirúrgica Infantil BFE 98%

Declaración de conformidad



Declaración UE de Conformidad

Fabricante **Diasia Biomedical Technology Co., Ltd.**
Domicilio **2F/3F301/4F (Edificio A)& 2F (EdificioB), FuXinLin Parque Industrial, Hangcheng
Zona Industrial, Taoyuan, Xixiang, Bao'an Distrito, Shenzhen, China**
EC Representante **CMC Medical Devices& Drugs S.L.**
C/ Horacio Lengo N° 18, CP 29006, Málaga, España
+34951214054

Producto: **Mascarillas quirúrgicas . No reutilizable.**

Modelo: **175mm × 94mm**

Clasificación (MDD, Anexo IX): **Clase I ReglaI**

Por la presente declaramos que los productos mencionados arriba cumplen con la transposición a la legislación nacional, las disposiciones de las siguientes Directivas y los Estándares de Consejo de EC. Todas las documentaciones de respaldo son conservadas en las facilidades del fabricante. Somos el único responsable del DOC.

DIRECTIVAS

Directivas generales aplicables:

Directiva de Dispositivos Médicos: DIRECTIVA DE CONSEJO 93/42/EEC de 14 de junio de 1993 relativa a dispositivos médicos(MDD 93/42/EEC).

Procedimiento de evaluación de conformidad: Directiva 93/42/EEC Anexo VII

Estándares:

EN 14683:2019;

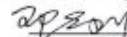
ISO 10993-5-2009;

ISO 10993-10:2010;

Todas las normas armonizadas aplicables (publicadas en el Diario Oficial de las Comunidades Europeas)

Fecha de marcado CE: Nov **12, 2020**

Lugar, Fecha: **Shenzhen, 12.11.2020**

Firma: 

Nombre/Puesto: Kirby Deng / G.M



Surgical mask / Surgical mask (Kids) BFE 98%

Declaration of Conformity



EU Declaration Of Conformity

Manufacturer **Diasia Biomedical Technology Co., Ltd.**
Address **3th B,4th Floor, Building No.4, Chuangfu Industrial Park, Xixiang Tiegang Reservoir Road, Baoan District, Shenzhen, China**
EC Representative **M/sCMC Medical Devices& Drugs S.L.**
C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain
+34951214054

Product: **Disposable Medical Mask**

Model: **175mm×94mm , 145mm×94mm , 150mm×65mm**

Classification (MDD, Annex IX): **Class I Rule1**

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 DOC.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standards:

EN 14683:2019;

ISO 10993-5:2009;

ISO 10993-10:2010;

All applicable harmonized standards (published in the Official Journal of the European Communities)

Date CE mark was affixed: **May 12, 2020**

Place, Date: **Shenzhen, 12.05.2020**

Signature: *Kirby Deng* General Manager

Name/Position: Kirby Deng / G.M.

Medizinische Gesichtsmaske / Medizinische Gesichtsmaske (für Kinder) BFE 98%

EU-KONFORMITÄTSERKLÄRUNG



EU Declaration Of Conformity

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