

# Mascarilla Quirúrgica / Quirúrgica Infantil BFE 98%

Declaración de conformidad



## 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 Nº 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: *Kathy Deng* General Manager

Name/Position: **Kathy Deng / G.M.**

# Surgical mask / Surgical mask (Children) BFE 98%

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