

EU Declaration of Conformity

Manufacturer: Dongguan LingJin Precision Manufacturing Co.,LTD.
Room 301 Building 7, No.6 Yuyuan Second Road, Huangjiang
Town, Dongguan, Guangdong, China 0769-89769005

European Representative: CMC Medical Devices & Drugs S.L.
Horacio Lengo N° 18, CP 29006, Málaga, Spain

Product Name: Disposable Medical Face Mask
Specification: 17.5cm×9.5cm, 14.5cm×9.5cm
UDI-DI: 12-458

Classification (MDD, Annex IX): Class I, Rule 1.

Conformity Assessment Route: Annex VII of MDD 93/42/EEC.

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.

The manufacturer is exclusively responsible for the declaration of conformity.

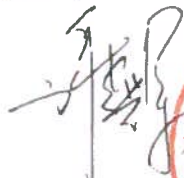
General applicable regulations, directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Applied standards:

EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010.

Signature:



Name:

Position:

General Manager

Place/date:

2020-05-13



File No.: GDLJ/CE01, Ver.A/0