

CE *EC Declaration of Conformity* CE

Manufacturer: Hubei Mingerkang Health & Safety Appliances Co., Ltd.
No.1, Dutai Industrial Park, Xiantao City, Hubei Province,
China

SRN: CN-MF-000003241

Whose Single Authorized EU-Representative: Riomavix S.L.

Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain

SRN: ES-AR-000001202

Product Name: Disposable Medical Face Mask

Product Model: Flat-type: 19.5*9.5cm, 17.5*9.5cm, 14.5*9.5cm, 12.5*9cm,
other sizes customizable upon request

EMDN Code: T0204

Basic UDI: 697047812A00014N

Intended Disposable protective non-woven products for daily
purpose of device: isolation protection

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation 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:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance.
ISO:15223-1:2021, ISO 20417:2021,ISO 13485:2016, EN ISO 14971:2019,
ISO/TR 24971:2020,EN ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021,
ASTM D4169-2022, MEDDEV. 2.7.1 Rev.4.

Validity:2024/12/06-2029/12/05

Signature: 
Name: *Bella Wang*
Title: General manager
Place/Date: China, Dec 12, 2024