

CE DECLARATION OF CONFORMITY

Name and address of the manufacturer:/

G.R.M.E. CO.,LTD
Yin Sha Industrial Park,
Zengcheng District, Guangzhou

EC Authorized Representative:/

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

We declare under our sole responsibility that:

Name of the medical device:/

Disposable Medical Mask (Non-sterile)

Type:/

Type IIR

Product code:/

UMDNS code 12447(Masks,Medical)

Intended purpose:/

The Disposable medical mask is intended to be worn to protect against the spread or transmission of infectious germs in a general medical facility. The main aim is to protect the patient against infectious germs. In addition, in certain situations the wearer should be protected against splashes of potentially contaminated liquids and viable particles.

Basic UDI-DI:/

NA

Trade name:/

None

Of class:/

Rule1, Class I
according to annex IX of Regulation(EU)93/42/EEC

CS reference:/

NONE

Applicable standards:/

EN 14683:2019+AC:2019
EN ISO 10993-5:2009
EN ISO 10993-10:2013

Conformity assessment:/

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC and 2007/47/EC for medical devices as transposed into national law. All supporting documentation is retained under the premises of the manufacturer.

CE

Guangzhou P.R. April 20th 2020

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione



Jiangdaosong, Manager