

EU Declaration of Conformity

Manufacturer:

Hubei Qianjiang Kingphar Medical Material Co., Ltd.

Yuanguang Road, 433100, Qianjiang, P. R. China

European Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

Declares that the MDD described hereafter

Product Name and Model

Product code JHFM004

Medical Mask TYPE IIR - EN 14683 - Disposable Non-Woven Face mask, Ear-Loop, 3-PLY, Non Sterile

Meet the provisions of the Council Directive 93/42/EEC & 2007/47/CE which apply to them.

Harmonized standards or normative documents: EN 14683:2019

GMD Code: 35177

UMDNS Code: 12458

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

Conformity Assessment Route: Annex VII of MDD

The devices in object meet the essential requirements of the Directive 93/42/CEE (Annex I) as amended by Directive 2007/47/CE.

We herewith declare in our own responsibility that the above mentioned product meet the transposition into national law, the provisions of the following Medical Device Directive (MDD) 93/42/CEE as amended by Directive 2007/47/CE, and it is conforming with applicable technical standards.

All supporting documentations are retained under the premises of the manufacturer.

Technical File and supporting documentation are retained under the premises of the Manufacturer at disposition of the Competent Authorities for 5 years. In addition, the manufacturer has implemented and maintains a procedure for the post-market surveillance and vigilance system.

Name and Surname: Wang zhongxiao

Position: President

Date: May 14, 2020

Signature: 