

EC Declaration of Conformity

Manufacturer: Henan Huibo Medical Co., Ltd.
Weishi Road Central, Nanyang New Energy Economic and
Technological Development Zone, Nanyang City, Henan,
China

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Product Name: Disposable medical face mask
Medical Surgical Mask
UMDN Code: 12458

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

Conformity Assessment Route: EC DECLARATION OF CONFORMITY
following the 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 Directive
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 93/42/EEC.

Applied standards, common specification, guidance:
EN 14683:2019+AC:2019, EN ISO 15223-1:2018, EN 1041:2008+A1:2013,
EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO
10993-5:2009, ISO 10993-10:2010.

Signature: *Zhu Tiangang*

Name:
Position: General Manager

Place/date: Nanyang City, Apr. 05, 2020



EC Declaration of Conformity

Manufacturer:

whose single Authorized EU-Representative:

Henan Huibo Medical Co., Ltd.

Weishi Road Central, Nanyang New Energy
Economic and Technological Development
Zone, Nanyang City, 473000, Henan Province,
The peoples republic of China

Prolinx GmbH

Registered address: Brehm str. 56, 40239,

Duesseldorf, GERMANY

Contact Person: Mr. Nianzhuang Liu

E-Mail: med@eulinx.eu

Tel: 0049 211 3105 4698

Fax: 0049 2131 4051968-9

We, the manufacturer, herewith declare that the products

Disposable medical face mask
Disposable mask
Medical surgical mask
N95 respiratory protective mask

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Henan Huibo Medical Co., Ltd

Weishi Road Central, Nanyang New Energy Economic and Technological Development
Zone, Nanyang City, 473000, Henan Province, The peoples republic of China

签署地址 时间 (手签)

Place, date

职位 签名 (手签) 盖公章

Legally binding signature, Function

EC Declaration of Conformity

