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

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 15223-1:2016, 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 Tiang ang

Name:
Position: General Manager

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

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