Declaration of Conformity

Manufacturer: Hunan EEXI Technology & Service co.,LTD..
Address: No. 6 North of Pingtou Road, Liuyang Hi-tech Industrial Development Zone, Hunan China.

EC Representative: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Device Name and Type:
Device name: Disposable surgical face mask
Type: Type IIR

Classification and Conformity Route:
According to 93/42/EEC Annex IX, Rules 1, all non-invasive devices are in Class I, unless one of the rules set out hereinafter applies. The Conformity Route is Annex VII EC declaration of conformity.

We, Hunan EEXI Technology & Service co.,LTD. herewith declare on our exclusive responsibility 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.

The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product .

Harmonized Standards:
All applicable harmonized Standards (published in the Official Journal of the European Communities)
Please see Annex List.

Name/Position: Liuxiangfu /General Manager

Signature: _____ **Date:** 2020. 4. 3

Annex:

Harmonized Standards List

Standards	Standard's title
ISO 13485:2016	Medical Devices - Quality management systems - Requirement for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1: 2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
MEDDEV 2.7.1: REV4.	Evaluation Of Clinical Data : A Guide For Manufacturers and Notified Bodies
EN 14683:2019	Medical face masks – Requirements and test methods
EN ISO 10993-1: 2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5: 2009	Biological evaluation of medical devices-Part 5: Test for In Vitro Cytotoxicity.
EN ISO 10993-10: 2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.