

EU Declaration of Conformity

Manufacturer: Hunan Zhenheyikang Medical Instrument Co.,Ltd
NO.6 Building Jingxiang Energy, NO.55 Xiaguang East Road,
Gaoxin District, Xiangtan, Hunan, China

SRN:

European Representative: SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
SRN:

Product Name: Disposable medical mask (sterile)
Models: Ear loop, Tie on.
Classification: Type I, Type II, Type IIR.
GMDN Code: 35177
CAN Code: T020699
UDI-DI:

Classification (MDR, Annex VIII): Class Is, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Annex XI part A + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.
Hunan Zhenheyikang Medical Instrument Co.,Ltd. is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidances:

EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ISO 11135:2014, EN ISO 11607-1:2017, EN ISO 11607-2:2017, EN ISO 11737-1:2018, EN ISO 11737-2:2019, ASTM D4169-2016, MDCG 2019-15.

Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP,
Amsterdam, Netherlands

NB Identification number: 2797
(EC) Certificate(s): Not yet
Expire date of the Certificate: Not yet
Start of CE Marking: Not yet

Signature:

Yilin Yin

Name: Yilin Yin

Position: General Manager

Place/date Xiangtan City, 08/11/2020