

EU Declaration of Conformity

Manufacturer:

Trois - rivières sino-american Medical Devices Co. , Ltd
North Yingbin road, Yanjiao Economic and Technological
Development Zones, Sanhe City, Langfang City, Hebei Province

European representation:

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

We, the manufacturer, herewith declare that the products

Disposable Medical Masks

UMDN-Code: 12-447

Standards applied:

EN 1041:2008 Information supplied by the manufacturer with medical devices

EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements

ISO 10993-1:2018 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: Tests for in vitro cytotoxicity

EN ISO 10993-10:2013 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EN 14683: 2019 Medical face masks-Requirement and test method

EN ISO 14971:2012 Medical devices - Application of risk management to medical devices

EN 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

Meet the provisions of Directive (EU)2017/745 which apply to them.

The medical device has been assigned to class I according to Rule 1, Annex VIII of the Directive (EU)2017/745.
It bears the mark



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

Company: Trois - rivières sino-american Medical Devices Co. , Ltd

Address: North Yingbin road, Yanjiao Economic and Technological Development Zones, Sanhe City, Langfang City,
Hebei Province

16 April 2020

Place, date

Ren zhi wei

Legally binding signature, Function



File no.: CE-TF-09 A/0