



EC Declaration of Conformity

Manufacturer: [REDACTED]

Address: [REDACTED]
[REDACTED]
Shenzhen, China

EU Representative: Share Info Consultant Service LLC Repräsentanzbüro

Address: Heerdter Lohweg 83, 40549 Deutschland.

Device name: Disposable surgical mask (non-sterile)

Model: MP211, MP212, MP213

Classification and conformity Route:

According to 93/42/EEC Annex IX, Rule 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 herewith declare 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 the declaration of conformity is limited by the issuing of the revised declaration of conformity.

Harmonized Standards:

ISO 10993-1:2018

EN ISO 14971:2012

ISO 10993-5:2009/AC 2010

EN ISO 15223-1:2016

ISO 10993-10: 2010

EN 1041:2008

MEDDEV 2.7.1 REV 4.0

EN 14683:2019

Signature: 

Date: 15 May 2020

Name/Position: General Manager

