

Declaration of Conformity



Name and address of Registered Manufacturer: B. J. ZH. F. Panther Medical Equipment Co., Ltd
Floor 3, Building 1, 28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China.

Name and address of Authorized Representative: Obelis s.a.
Bd. Général Wahis 53 B-1030 Brussels, Belgium

Product name: Non-sterile Medical Face Masks

Product type/model: Ear hook type, Strap type. (KR, KF, XS, XXS, S,M,L,XL,XXL,XXXL, SL,SSL. Rectangle, Boat, Arch, Square, Circle, Trapezoid)

This declaration confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive: Medical Device Directive 93/42/EEC

Conformity assessment procedure: EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)

Classification: Class I according Rule 1 of Annex IX of Directive 93/42/EEC

Applied normative documents: EN 14683:2019

Applied Quality Management System EN ISO 13485:2016

This DoC will remain valid only if Quality Management System Certificate remains valid and the surveillance audits are conducted.

Evaluation has been carried out in accordance with test reports made by National Medical Products Administration Jinan Quality Supervision and Inspection Center for Medical Devices.

No. of test report: W2020032731; S2020032087

Issue date: 21.03.2020

21.03.2025

Expiration date:

This declaration applies to products having the same attributes(parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.



B. J. ZH. F. Panther Medical Equipment Co., Ltd