



Attestation of Conformity

No. ICR Polska/M8911820



**Name and address
of Registered Manufacturer:**

Hunan Hengyue Protection Technology Co.,Ltd
2/F,building 4,standardization workshop,Hengdong Economic
Development Zone,Hunan Province

Product name:

Disposable medical mask (non sterile)

Product type/model:

plane lug type

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

The assessment process has been carried out in accordance with the program PC-P-07-07.

Evaluation has been carried out in accordance with test reports made by European Quality Test Co., LTD.

No. of test report:

EQT-2003-0329-MDD

Issue date:

18.03.2020

Expiration date:

17.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-9018.

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



Director: Rafał Kalinowski

Warsaw, 18. 03. 2020.



ICR Polska Co. Ltd.

ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com