



Attestation of Conformity

No. ICR Polska/M6330218



Name and address of Registered Manufacturer: Shenzhen Zhishan Medical Co., Ltd
RM01, 2/F, Building B, Tongzhou Electronic Longgang Factory
No.1 Road5, Baolong Community, Baolong Street, Longgang Area, Shenzhen, Guangdong, China

Product name: Standard Earloop Medical Mask

Product type/model: ZSC001, ZSE001

Trade mark: 都宁®

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 n/a

This AoC will remain valid only if Quality Management System Certificate remains valid. 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 report made by:

- SHENZHEN CTO TECHNOLOGY CO., LTD

No. of test report: CTO200313012CRS

Issue date: 24.03.2020

Expiration date: 23.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3125.

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



Director: Rafał Kalinowski

Warsaw, 24. 03. 2020.

ICR Polska Co. Ltd.

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