International Certification Registrar International Certification Registrar International Certification Registrar

Attestation
of Conformity

No. ICR Polska/M8911320

CE

Name and address of Registered Manufacturer:	Jiangsu taierkang medical technology co.LTD 3rd floor,building 5,liyuan Development Zone 06-4 Plots(Dicui Road #100),Binhu District,Wuxi City.
Product name:	Single-use medical face mask
Product type/model:	TEK-001A,TEK-002A

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-2003-0331-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/2020-9013.

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.

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