6、CE认证





No. ICR Polska/M7710109

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Name and address Yunnan Tianyu Medical Equipment Co., Ltd

of Registered Manufacturer: Floor 1, building 24, poverty alleviation workshop, industrial park, Zhaoyang District, Zhaotong City, Yunnan Province

Product name:

Product type/model: 175mm*95mm*3 (non-sterile)

n/a Trade mark:

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 EC Declaration of Conformity (Annex VII of Directive

procedure:

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

Applied normative documents: EN 14683:2019+AC:2019

Applied Quality Management System

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:

UAC Quality Technology Service (UK) Ltd

No. of test report: TCF-UAC-20200323069MDD

25.03.2020 Issue date: **Expiration date:** 24.03.2025

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, 25. 03. 2020.

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