



# Attestation of Conformity

No. ICR Polska/M8508520



**Name and address  
of Registered Manufacturer:**

Jiangxi AICARE Medical Technology Co., Ltd.  
South Side of South Ring Road, Le'an County, Fuzhou City, Jiangxi  
Province (Building No. 1, New Era Home Group, Le'an  
County).

**Product name:**

Infrared thermometer

**Product type/model:**

A66,A68,A69

**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 60601-1:2006+A12:2014 EN 60601-1-2:2015

**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:**

RBT200320211SR-1

**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/2020-8585.

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, 24. 03. 2020.



**ICR Polska Co. Ltd.**

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