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ISTITUTO SERVIZI EUROPEI TECNOLOGICI

CERTIFICATE

Certificat - Certificado- Сертификат - *Zertifikat - 证书*

1) **APPLICANT:** (who finally puts the product on the market)

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). China.

2) **CERTIFICATE NO.:** ISETC001720200310

FILE REFERENCE: BNK-20(02)-0(5019I-MDD

3) **ISET MARK:**

4) **CAUTION ABOUT CE MARKING** (instructions for the applicant who puts the product on the EU market):

The label of the CE Mark, [illegible] not less than 5mm height, CE Marking and EC Declaration of Conformity are [illegible] the manufacturer or its applicant who puts the product on the market. This one is responsible [illegible] CE marking and certification procedure as required by the legislation in force. Only for the products which are compliant [illegible] specific Directives or Regulations will be necessary to appoint a Notified Body.

5) **TYPE OF PRODUCT:** Infra[illegible] thermometer

MODEL(S): *M6, M68, M69, A7A*

6) **LIST OF DIRECTIVES / REGULATIONS /STANDARDS** (as declared by the manufacturer itself)

Medical Device Directive 93/42/EEC

EN 60601-1:2006+A12:2014, EN 60601-1-2:2015, EN ISO 13485:2016/AC:2016,

EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 10993-1:2009/AC:2010

7) **NOTE:** The applicant is aware about the contents and information included in the MoH/09804.06 Regulation for this type of Certificate that is considered totally accepted. The latest revision of the Regulation is available and can be downloaded from the website www.iset-italia.eu. This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO/IEC 17065:2012 or European Regulation 765/2008.

8) **REMARK:** Certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the ISET Mark (at point 3) on their products, even if it doesn't imply any assessment on the safety and compliance of the product. ISET declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.

9) **DATE OF ISSUE:** 14/03/2020 **EXPIRY DATE:** 19/03/2025

10) **SIGNATURE:** Li Zhang

(On behalf of the Legal representative)

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