


**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING
MEDICAL DEVICES**

 **Manufacturer:** Shenzhen Finicare Co., Ltd
201, Dehe Building, No. 81, Haoyong No.2 Industrial Park, Hongxing Community, Songgang
Street, Bao'an District, Shenzhen, China
Tel:+86-755-23013503
Fax:+86-755-23574425

MEDICAL DEVICE: Infrared Thermometer
MODEL: FC-IR100, FC-IR101, FC-IR200, FC-IR300, FC-IR400

CLASSIFICATION-ANNEX IX: CLASS IIA, RULE 10
CONFORMITY ASSESSMENT ROUTE: ANNEX II(excluding Section 4)

**WE, Shenzhen Finicare Co., Ltd, AT OUR SOLE RESPONSIBLE HERewith DECLARE
THAT BODY MODE OF THE STATED MEDICAL DEVICES
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL
DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE
2007/47/EEC ALL SUPPORTING DOCUMENTATION IS PETAINED AT THE PREMISES
OF THE MANUFACTURER.**

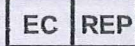
**AND are in conformity with the national standards transposing harmonised standards:
EN ISO 13485:2015; EN ISO 14971:2012; EN 1041:2008+A1:2013; EN62304:2000+A1:2015;
EN 60601-1-6:2010+A1:2015; EN62366-1:2015
EN 60601-1:2006+A1:2013; EN60601-1-2:2015; EN60601-1-11:2015; EN ISO 80601-2-56:2017**

NOTIFIED BODY: TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 MÜNCHEN, Germany
Website: www.tuv-sud.cn

IDENTIFICATION NUMBER
(EC) CERTIFICATE(S): G2 004665 0002 Rev. 00
Issue date: 2019-05-08
Expiry date: 2024-05-07



EUROPEAN REPRESENTATIVE: Share Info Consultant SerUce LLC Repr.sentanzbQro



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START OF CE-MARKING: ISSUE DATE OF EC CERT

PLACE, DATE OF DECLARATION CHINA GUANGDONG PROVINCE 2020.11.10

For and on behalf of
SHENZHEN FINICARE CO., LTD

SIGNATURE: *Charry Li*

NAME: CHARRY Li. 李超.....

POSITION:(RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)