

DECLARATION OF CONFORMITY
TO REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF
THE COUNCIL OF 5 April 2017 ON MEDICAL DEVICES



Manufacturer: Hetaida Technology Co., Ltd.

Room 801, 802, 803, 804, 901, 2# Building Scientific Research Center, Songhu Intelligent Valley, No.6 Minfu Road, Liaobu Town, Dongguan City, Guangdong Province, P.R.China.

SRN: CN-MF-000032793

Medical Device: Infrared Body Thermometer

Model: HTD8813, HTD8818A, HTD8819, HTD8808C, HTD8816C, HTD8823EU

Basic UDI-DI: 6970289038800132 EMDN code: V0301010202

Intended purpose: The Infrared Body Thermometer is designed to be used for intermittent measurement and monitoring of human body temperature by consumers in the home setting and primary care setting as screening tool.

Classification: Class IIa, According to Regulation (EU) 2017/745, Annex VIII, Rule 10.

Conformity assessment Route: Annex IX of Regulation (EU) 2017/745.

We, Hetaida Technology Co., Ltd., herewith declare that at our sole responsibility the stated medical devices (Infrared Body Thermometers) meet the transposition into national law, the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

All supporting documentation is retained at the premises of the manufacturer.

The above medical devices are in conformity with the national standards transposing harmonised standards: EN ISO 13485: 2016+A11:2021; EN ISO 14971:2019+A11:2021; EN ISO 20417:2021; EN ISO 15223-1:2021; EN 62304:2006+A1:2015; EN 60601-1-6:2010+A1:2015+A2:2021; EN 62366-1:2015+AC:2015+AC:2016+A1:2020; EN 60601-1:2006+A1:2013+A2:2021; EN 60601-1-2:2015+A1:2021; EN 60601-1-11:2015+A1:2021; EN ISO 80601-2-56:2017+A1:2020, EN ISO 10993-1:2020.

Notified Body: SGS FIMKO OY

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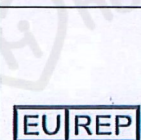
E-MAIL: sgs.fimko@sgs.com

Website: www.fi.sgs.com

Identification number:  0598

(EC) Certificate(s) No.: FI26/1008034

Start of CE-marking: 09-30-2026



European Representative:

SUNGO Europe B.V.

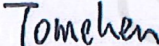
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Place, Date of Declaration:

China GUANGDONG PROVINCE, 10-24-2026

Signature: 

Name: Tom Chen 陈振光

Position: General Manager (responsible Senior Executive of manufacturer)

