

EU Quality Management System Certificate FI26/1008034

The quality management system of

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

has been assessed and certified as meeting the requirements of
Regulation (EU) 2017/745 Annex IX (I and III)

for the following:

Blood Pressure Monitors, Infrared Thermometers

Issue 1

Previous certificate's number and issue: N/A

Change in between this certificate and the previous one: N/A

The devices covered, their risk classifications, codes applied, identification details, intended purposes, standards and common specifications followed, conditions or limitations, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 30 September 2026 until 29 September 2031 and remains valid subject to satisfactory surveillance audits.

Certified since 30 September 2026

Certified activities performed by additional sites are listed on the subsequent pages.

Authorised by
Teuvo Vaara, Certifier

SGS FIMKO OY

Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 - www.sgs.fi - Business ID 0634247-4

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Hetaida Technology Co., Ltd.



Regulation (EU) 2017/745 Annex IX (I and III)

Issue 1
Sites
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
Management, Design, Development, Purchase, Manufacture, Quality Control, Warehouse, Sales

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Regulation (EU) 2017/745 Annex IX (I and III)

Attachment 1 of Issue 1

Risk classes, codes, identification, and other relevant details of the certified devices:

Risk class Ila

MDA 0203, MDS 1009, MDT 2010, MDT 2011

EMDN code: Z1203020501 - Non-invasive oscillometric blood pressure gauges

Device Name: Electronic Blood Pressure Monitor, Basic UDI-DI: 69702890366001ZT, Model: HTD6601EU, HTD6602EU, HTD6603EU HTD6605EU, D6606EU, D6607EU

EMDN code: V0301010202 - Non-contact digital thermometers

Device Name: Infrared Body Thermometer, Basic UDI-DI: 6970289038800234, Model: HTD8216C, HTD8219EU, HTD8222EU, H8228EU

Device Name: Infrared Body Thermometer, Basic UDI-DI: 6970289038800132, Model: HTD8813, HTD8818A, HTD8819, HTD8808C, HTD8816C, HTD8823EU

Device Name: Infrared Ear Thermometer, Basic UDI-DI: 69702890382001ZM, Model: HTD8208C

The certification decision is based on the following:

Report Identification and Date:

Audit report: MDR-2039_Hetaida_2026V1_FPMREG3019 - MD Audit Report Ver I Rev.1, dated 2026-08-14

Technical documentation assessment reports: MDR-2039_Hetaida_BPM_FPMREG3020 - MDR Technical Documentation Assessment Report Ver J Rev.1, dated 2026-07-28; MDR-2039_Hetaida_Infrared Body Thermometer_FPMREG3020 - MDR Technical Documentation Assessment Report Ver J Rev.1, dated 2026-07-28

Applied Standards / Common specifications:

EN ISO 13485:2016 + A11/2021, EN ISO 14971:2019 + A11/2021, EN ISO 15223-1:2021, references to other relevant CS and harmonized standards are in the reports

Conditions for or limitation to the validity of the certificate:

N/A

EU Authorised Representative:

SRN: NL-AR-000000247, SUNGO Europe B.V.

Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands.



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