EC Certificate Full Quality Assurance System FI17/07005

The 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

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex II (excluding section 4)

For the following products

Infrared Body Thermometers
Infrared Ear Thermometers

Products covered and additional sites are listed in Attachment 1 of this certificate

This certificate is valid from 06 April 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 9 May 2017
This certification is based on decision: FI20/07030P0

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Authorised by

Jani Högman
Certifier

SGS Fimko Ltd., Notified Body 0598
Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

DECISION

06 April 2020 FI21/07030P0

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

EC-certification application 17/064-8, dated 2021-04-06

Subject

Certification amendment, due P.R. China address regulation change, based on Council Directive 93/42/EEC concerning medical devices, Annex II Section 3 (excluding Section 4). New addresses listed below.

Manufacturer

Manufacturer	Hetaida Technology Co. Ltd	
Address	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	
Other Addresses covered by the certificate	Location	Activity at the location
	Room 401,501,601, 2# Building, No.501,Dalingshan Section, Guanchang Road,Dalingshan Town, Dongguan City, Guangdong Province, P.R. China	Production, inspection, logistics

Decision

A certificate will be issued for the manufacturer. The certificate covers the following products:

Product	Model	Class
Infrared Body Thermometer	HTD8818A	IIa
Infrared Body Thermometer	HTD8808C	IIa
Infrared Body Thermometer	HTD8816C	IIa
Infrared Body Thermometer	HTD8813	IIa
Infrared Body Thermometer	HTD8819	IIa
Infrared Ear Thermometer	HTD8208C	IIa
Infrared Body Thermometer	HTD8216C	IIa
Infrared Body Thermometer	HTD8222EU	IIa
Infrared Body Thermometer	HTD8219EU	IIa
Infrared Body Thermometer	HTD8823EU	IIa

Justification

SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex II (excluding Section 4) of Medical Device Directive 93/42/EEC. The decision is based on Notification of Change, date 14 Jan 2014 and Physical address Conformance Statement, date 24 Feb 2021

The manufacturer has signed the undertaking to follow the obligations of Annex II of the Directive 93/42/EEC.

Certificate related to decision

FI17/07005, Issue 4

Attachment to certificate

Attachment 1

Valid until

This decision is valid until 24 May.2024 providing the requirements of the certification are fulfilled.

Date

Helsinki, 06 April 2021

Jani Högman, Certifier
SGS Fimko Ltd, Notified Body 0598

Attachment 1 to SGS Fimko Ltd. EC certificate FI17/07005 Issue 4

Manufacturer	Hetaida Technology Co., Ltd	
Address	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	
Other Addresses covered by the certificate	Location	Activity at the location
	Room 401,501,601, 2# Building, No.501,Dalingshan Section, Guanchang Road,Dalingshan Town, Dongguan City, Guangdong Province, P.R. China	Production, inspection, logistic,

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

Medical Device	Class	Model/type nr. and Trademark(s)
Infrared Body Thermometer	IIa	HTD8818A
Infrared Body Thermometer	IIa	HTD8808C
Infrared Body Thermometer	IIa	HTD8816C
Infrared Body Thermometer	IIa	HTD8813
Infrared Body Thermometer	IIa	HTD8819
Infrared Ear Thermometer	IIa	HTD8208C
Infrared Body Thermometer	IIa	HTD8216C
Infrared Body Thermometer	IIa	HTD8222EU
Infrared Body Thermometer	IIa	HTD8219EU
Infrared Body Thermometer	IIa	HTD8823EU

Letter of Confirmation #2

03 May 2024

FI24/07185P0

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

Notified Body Letter of Confirmation

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, SGS Fimko Ltd, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0598 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following 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

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Helsinki, 03 May 2024

Seppo Vahasalo, Notified Body Manager
SGS Fimko Ltd

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Infrared Body Thermometer Model: HTD8818A, HTD8808C, HTD8816C, HTD8813, HTD8819, HTD8216C, HTD8222EU, HTD8219EU, HTD8823EU	Class IIa	N/A	FI17/07005, Issue 4 NB0598
Infrared Ear Thermometer Model: HTD8208C	Class IIa	N/A	FI17/07005, Issue 4 NB0598

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A