



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

Authorised by


Jani Högman
Certifier



仅限振海生产的体温计销售之用
有效期至: 2021年12月31日

SGS Fimko Ltd., Notified Body 0598
Takomitie 8, FI-00380 Helsinki, Finland
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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	Ila	HTD8818A
Infrared Body Thermometer	Ila	HTD8808C
Infrared Body Thermometer	Ila	HTD8816C
Infrared Body Thermometer	Ila	HTD8813
Infrared Body Thermometer	Ila	HTD8819
Infrared Ear Thermometer	Ila	HTD8208C
Infrared Body Thermometer	Ila	HTD8216C
Infrared Body Thermometer	Ila	HTD8222EU
Infrared Body Thermometer	Ila	HTD8219EU
Infrared Body Thermometer	Ila	HTD8823EU

仅限振海生产的体温计销售之用

有效期至: 2021 年 12 月 31 日。

与振海公章同时使用方有效

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 certificates	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	Ila
Infrared Body Thermometer	HTD8808C	Ila
Infrared Body Thermometer	HTD8816C	Ila
Infrared Body Thermometer	HTD8813	Ila
Infrared Body Thermometer	HTD8819	Ila
Infrared Ear Thermometer	HTD8208C	Ila
Infrared Body Thermometer	HTD8216C	Ila
Infrared Body Thermometer	HTD8222EU	Ila
Infrared Body Thermometer	HTD8219EU	Ila
Infrared Body Thermometer	HTD8823EU	Ila

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

有效期至: 2021 年 12 月 31 日.

Attachment to certificate

Attachment 1

与振海公章同时使用方有效

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

SGS Fimko Ltd

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Business ID 0978538-5

Member of the SGS Group (SGS SA)