

EC Certificate Full Quality Assurance System FI17/07005

The management system of

# Hetaida Technology Co. Ltd

4F, BaiShiDa High-Tech Park, XiangDong Industrial Area,  
DaLingShan Town, DongGuan City  
Guangdong, China

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC on Medical Devices, Annex II (excluding section IV)

For the following products

**Infrared Body Thermometer**  
**Infrared Ear Thermometer**

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 11 March 2020 until 9 May 2022  
and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 9 May 2017

This certification is based on decision: FI20/07008P0

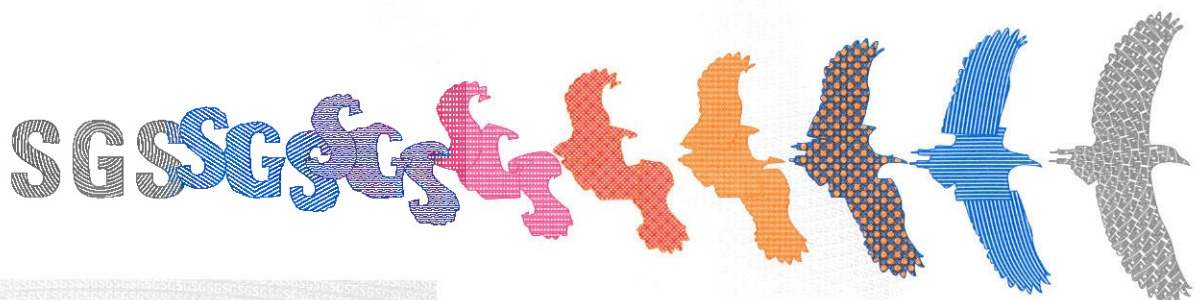
Authorised by

Tom Törn  
Certification Director



SGS Fimko Ltd., Notified Body 0598

P.O. Box 30 (Särkiniementie 3), 00211 Helsinki, Finland  
t +358 9 696 361 f +358 9 692 5474 www.sgs.com



## Attachment 1 to SGS Fimko Ltd. EC certificate FI17/07005 Issue 2

<b>Manufacturer</b>	Hetaida Technology Co. Ltd
<b>Address</b>	4F, BaiShiDa High-Tech Park, XiangDong Industrial Area, DaLingShan Town, DongGuan City Guangdong, China
<b>Activity and Medical Device Product Category</b>	93/42/EEC Annex II (excluding Section 4) Infrared Body Thermometer Infrared Ear Thermometer

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

Medical Device	Class	Trademark(s) and Model(s)/type(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



Hetaida Technology Co. Ltd  
4F, BaiShiDa High-Tech Park, XiangDong Industrial Area,  
DaLingShan Town, DongGuan City  
Guangdong, China

EC-certification application 17/064-04 date 2019-08-06

**Subject** Certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex II Section 3 (excluding Section 4).

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**Manufacturer** Hetaida Technology Co. Ltd  
4F, BaiShiDa High-Tech Park, XiangDong Industrial Area,  
DaLingShan Town, DongGuan City,  
Guangdong, China

**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

**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 Technical File Review report(s) 288258 dated 2019-12-24 and 2019-12-09

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 2

**Attachment to certificate** Attachment 1

**Valid until** This decision is valid until 9 May.2022 providing the requirements of the certification are fulfilled.

**Date** Helsinki, 11 March 2020



Tom Törn, Certification Director  
SGS Fimko Ltd, Notified Body 0598