SGS

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

Page 1 of 2









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

Manufacturer	Hetaida Technology Co. Ltd	
Address	4F, BaiShiDa High-Tech Park, XiangDong Industrial Area, DaLingShan Town, DongGuan City Guangdong, China	
Activity and Medical Device Product Category	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	lla	HTD8818A	
Infrared Body Thermometer	lla	HTD8808C	
Infrared Body Thermometer	lla	HTD8816C	
Infrared Body Thermometer	lla	HTD8813	
Infrared Body Thermometer	lla	HTD8819	
Infrared Ear Thermometer	lla	HTD8208C	
Infrared Body Thermometer	lla	HTD8216C	