



TITOLO

DICHIARAZIONE / DECLARATION

Doc. N° TH1003Rev. 0Pag. 1 di 1

LA DITTA LAICA SPA V.LE DEL LAVORO 10, FRAZ. PONTE – 36048 BARBARANO MOSSANO (VI) /THE COMPANY LAICA S.p.A. V.LE DEL LAVORO 10, FRAZ. PONTE – 36048 BARBARANO MOSSANO (VI)

DICHIARA CHE
DECLARES

IL CODICE ARTICOLO / ITEM CODE HTD8813

PRODOTTO DA / MANUFACTURED BY: Hetaida Technology Co., Ltd. 4F, BaiShiDa High-Tech Park, XiangDong Industrial Area, DaLingShan Town, DongGuan City, Guangdong - Chine

COPERTO DA CERTIFICATO / COVERED BY CERTIFICATE NO. FI17/07005-1

DATATO / DATED 09/05/2017

EMESSO DA / ISSUED BY SGS

CORRISPONDE AL CODICE COMMERCIALE LAICA / CORRESPONDS TO LAICA COMMERCIAL CODE TH1003

E QUINDI I DUE CODICI SI RIFERISCONO ALLO STESSO PRODOTTO / AS A CONSEQUENCE TWO ITEM CODES ARE REFERRING TO THE SAME PRODUCT.

DATA/ DATE: 18.03.19

FIRMA / SIGNATURE:

LAICA SPA
Viale del Lavoro, 10 - Fraz. Ponte
36021 BARBARANO MOSSANO (VI)
Tel. 0444/795314-795321 Fax 795322
Cod. Fisc. e Partita IVA 0028851046

Data / Date <u>18.03.19</u>	Emesso da / Issued by <u>[Signature]</u>	Approvato da / Approved by DIR <u>[Signature]</u>
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DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES



MANUFACTURER: HETAIDA TECHNOLOGY CO., LTD

4F, BAISHIDA HIGH-TECH PARK, XIANGDONG INDUSTRIAL AREA, DALINGSHAN TOWN, DONGGUAN CITY,
GUANGDONG, CHINA.

MEDICAL DEVICE: NON-CONTACT INFRARED BODY THERMOMETER

MODEL: HTD8808C, HTD8818A, HTD8816C, HTD8813, HTD8819

CLASSIFICATION - ANNEX IX: CLASS IIA, RULE 10

CONFORMITY ASSESSMENT ROUTE: ANNEX II (excluding Section 4)

WE, HETAIDA TECHNOLOGY CO., LTD., HEREBY DECLARE THAT

THE STATED MEDICAL DEVICES

MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF
14 JUNE 1993 CONCERNING MEDICAL DEVICES;

INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

AND ARE IN CONFORMITY WITH THE NATIONAL STANDARDS TRANSPOSING HARMONISED STANDARDS: EN ISO 13485:
2012+A1:2016; EN ISO 14971:2012; EN 1041:2008+A1:2013; EN ISO 15223-1:2012; EN 980:2008; EN
62304:2006+A1:2015; EN 60601-1-6:2010+A1:2015; EN 62366-1:2015;

EN 60601-1:2012; EN 60601-1-2:2015; EN 60601-1-11:2015; EN ISO 80601-2-56:2017

NOTIFIED BODY: SGS FIMKO OY

P.O. Box 30 (Särkiniementie 3)

00211 HELSINKI

COUNTRY: Finland

Phone: +358 9 696 361

Fax: +358 9 692 5474

E-MAIL: sgs.fimko@sgs.com

Website: www.fi.sgs.com

IDENTIFICATION NUMBER

(EC) CERTIFICATE(S):



EUROPEAN REPRESENTATIVE: WELLKANG LTD



SUITE B, 29 HARLEY STREET LONDON W1G 9QR, ENGLAND, UNITED KINGDOM

TEL: +44(20)30869438 FAX: +44(20)76811874

START OF CE-MARKING: **ISSUE DATE OF EC CERT**

PLACE, DATE OF DECLARATION: CHINA GUANGDONG PROVINCE 2017.12.12

SIGNATURE:

Tomchen

NAME: TOM CHEN 陈振光

POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)