

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES



MANUFACTURER: HETAI DA 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, HETAI DA 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

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IDENTIFICATION NUMBER

(EC) CERTIFICATE(S):



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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)