

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



MANUFACTURER: HETAI DA TECHNOLOGY CO., LTD
4F, BAI SHI DA 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., AT OUR SOLE RESPONSIBLE HEREWITH DECLARE THAT
BODY MODE OF 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: :2016; EN ISO 14971: 2012; EN 1041:2008+A1: 2013; EN 62304:2006+A1:2015;
EN 60601-1-6:2010+A1:2015; EN 62366-1:2015;

EN 60601-1:2006+A1:2013; 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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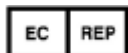
E-MAIL: sgs.fimko@sgs.com
Website: www.fi.sgs.com

IDENTIFICATION NUMBER

(EC) CERTIFICATE(S): FI17/07005



EUROPEAN REPRESENTATIVE: **WELLKANG LTD**



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

PLACE, DATE OF DECLARATION: CHINA GUANGDONG PROVINCE 2020.03.19

SIGNATURE:

Tomchen

NAME: TOM CHEN 陈振光

POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)