

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



MANUFACTURER: HETAIDA TECHNOLOGY CO., LTD
Room 801, 802, 803, 804, 901, 2# Building Scientific Research Center,
Songhu Intelligent Valley, No.6 Minfu Road, Liaobu Town, Dongguan
City, Guangdong Province, P.R.China
MEDICAL DEVICE: NON-CONTACT INFRARED BODY THERMOMETER
MODEL: HTD8816C

CLASSIFICATION - ANNEX IX: CLASS IIA, RULE 10
CONFORMITY ASSESSMENT ROUTE: ANNEX II (excluding Section 4)

WE, HETAIDA 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: 2019; 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

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IDENTIFICATION NUMBER

(EC) CERTIFICATE(S): FI17/07005



EUROPEAN REPRESENTATIVE: Share Info Consultant Service LLC Repräsentanzbüro



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START OF CE-MARKING: ISSUE DATE OF EC CERT

PLACE, DATE OF DECLARATION: CHINA GUANGDONG PROVINCE 2021.04.07

SIGNATURE:

Tomchen

NAME: TOM CHEN 陈振光

POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)



Manufacturer's Declaration

in relation to the Harmonised Standards update according to the COMMISSION IMPLEMENTING
DECISION of 14.4.2021, in particular with respect to:

- EN ISO 15223-1:2016 change to EN ISO 15223-1:2021;
- EN 60601-1-6:2010+A1:2015 change to EN 60601-1-6:2010+A1:2015+A2:2021;
- EN 62366-1:2015 change to EN 62366-1:2015+A1:2020;
- EN 60601-1:2006+A1:2013 change to EN 60601-1:2006+A1:2013+A2:2021;
- EN 60601-1-2:2015 change to EN 60601-1-2:2015+A1:2021;
- EN 60601-1-11: 2015 change to EN 60601-1-11:2015+A1:2021;
- EN ISO 80601-2-56:2017 change to EN ISO 80601-2-56:2017+A1:2020;

Tomchen

(Signature)

May 23, 2024

(Date)

Tom Chen

(Typed Name)

Position: (responsible Senior Executive of manufacturer)

