

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



MANUFACTURER: HETAI DA 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, 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: 2019; EN 1041:2008+A1: 2013; EN 62304:2006+A1:2015;
EN 60601-1-6:2010+A1:2015+ A2:2021; EN 62366-1:2015+A1:2020;
EN 60601-1:2006+A1:2013+ A2:2021; EN 60601-1-2:2015+ A1:2021; EN 60601-1-11:2015+A1:2021; EN
ISO 80601-2-56:2017+ A1:2020

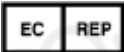
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IDENTIFICATION NUMBER

(EC) CERTIFICATE(S): FI17/07005



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START OF CE-MARKING: ISSUE DATE OF EC CERT

PLACE, DATE OF DECLARATION: CHINA GUANGDONG PROVINCE 2024.05.23

SIGNATURE:

Tomchen

NAME: TOM CHEN 陈振光
POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)

