

DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING

MEDICAL DEVICES



MANUFACTURER: Shenzhen Union Technology Co.,Ltd.

ADD: Floor 4-6th of Building D , Jiale Science&Technology Industrial Zone, No.3 ,
ChuangWei Road ,Heshuikou Community, MaTian Street, GuangMing New District, 518106
ShenZhen, PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: Infrared thermometer

MODEL: UFR101,UFR102,UFR103,UFR105,UFR106,UFR116,
UFR118,UFR205

CLASSIFICATION - ANNEX IX: CLASS IIA, RULE10

CONFORMITY ASSESSMENT ROUTE: ANNEX II(EXCLUDE II. 4)

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES;

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
WE ARE EXCLUSIVELY RESPONSIBLE FOR THIS DOC.

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED
EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER 0123

(EC) CERTIFICATE(S): G1 0786720014 REV.00



EUROPEAN REPRESENTATIVE: **Shanghai International Holding Corp. GmbH (Europe)**

ADD: Eiffestrasse 80, 20537 Hamburg, Germany

START OF CE-MARKING: APRIL 30, 2018

PLACE, DATE OF DECLARATION: SHENZHEN, AUGUST 17, 2020

SIGNATURE:

Malik Zhu

NAME: MALIK ZHU

POSITION: (GENERAL MANAGER)

