

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



MANUFACTURER:

NAME: SHENZHEN MEDEK BIO-MEDICAL CO., LTD.

Add: No. 101 Wenhao Industrial Part No. 13 Yuanxin Road Tongle Community,
Baolong Street Longgang District 518100 Shenzhen People's Republic of China

MEDICAL DEVICE: NAME: *Infrared Thermometer*

MODEL : MDI907, MDI111

CLASSIFICATION - ANNEX IX: CLASS IIb, RULE 10

CONFORMITY ASSESSMENT ROUTE: ANNEX II

WE, THE MANUFACTURER, HEREWITH 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.

NOTIFIED BODY:

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

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

No. G1.093979 0005 REV. 00



EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

START OF CE-MARKING:

PLACE, DATE OF DECLARATION:

SHENZHEN DATE: 05-09-2019

SIGNATURE

Liu Xiangming

NAME: LIU XIANGMING

POSITION: GENERAL MANAGER