

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



MANUFACTURER: *SHENZHEN AEON TECHNOLOGY CO., LTD.*
*RM6H02, BLOCK 27-29, TIANXIA IC INDUSTRIAL PARK, MAJIALONG, No.133 OF YIYUAN ROAD,
NANTOU STREET, NANSHAN DISTRICT, SHENZHEN, PEOPLE'S REPUBLIC OF CHINA.*

MEDICAL DEVICE: *INFRARED THERMOMETER A200*
UMDNS / EDMS(EDMA) CODE: 14036 GMDNS CODE: 14036

CLASSIFICATION - ANNEX IX: *CLASS IIA, RULE10*

CONFORMITY ASSESSMENT ROUTE: *ANNEX II (EXCLUDE.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 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.

ATTACHED: LIST OF STANDARDS

1. MDD 93/42/EEC
2. ISO13485:2016
3. IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012
4. EN 60601-1-2: 2015
5. IEC 60601-1-11:2015
6. ISO 80601-2-56:2017
7. EN ISO14971:2012
8. ISO10993-1:2018
9. ISO10993-5:2009
10. ISO10993-10:2010
11. EN 62304:2006/A1:2015
12. EN 62366-1:2015
13. ISO 15223-1:2016
14. EN1041:2008
15. MEDDEV 2.7.1: 2016 REV.4

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

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

NO. G1 073767 0013 REV.00



EUROPEAN REPRESENTATIVE:

SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE)
EIFFESTRASSE 80, 20537 HAMBURG, GERMANY

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START OF CE-MARKING:

AUG .2017

PLACE, DATE OF DECLARATION:

SHENZHEN, FEB. 3, 2019

SIGNATURE:

HUA XIE

NAME: HUA XIE

POSITION: GENERAL MANAGER

SHENZHEN AEON TECHNOLOGY CO., LTD.
深圳市正生技术有限公司
SHENZHEN CHINA
中国 深圳