

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 A202E UMDNS / EDMS(EDMA) CODE: 14036 GMDNS CODE: 17888
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. THE DECLARATION IS EXCLUSIVELY RESPONSIBLE BY THE MANUFACTURER.	
ATTACHED: LIST OF STANDARDS 1. ISO 13485: 2016 2. EN 60601-1: 2006/A2: 2021 3. EN 60601-1-2: 2015 /A1: 2021 4. EN 60601-1-11: 2015/A1: 2021 5. ISO 80601-2-56: 2017/A1: 2018 6. ISO 14971: 2019 7. ISO 10993-1: 2018 8. ISO 10993-5: 2009 9. ISO 10993-10: 2021 10. ISO 10993-23: 2021 11. EN 62304:2006/A1: 2015 12. EN 62366-1: 2015 13. EN 60601-1-6: 2005/A1:2012/A2:2020 14. ISO 17664: 2017 15. ISO 15223-1: 2021 16. EN 1041:2008+A1: 2013 17. MEDDEV 2.7.1: 2016 REV.4	
NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTRASSE 65, 80339 MUNICH, GERMANY
IDENTIFICATION NUMBER:	0123
(EC) CERTIFICATE(S):	NO. G1 073767 0013 REV.00
EUROPEAN REPRESENTATIVE:	SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE) EIFFESTRASSE 80, 20537 HAMBURG, GERMANY
START OF CE-MARKING:	SEP. 2023
PLACE, DATE OF DECLARATION:	SHENZHEN, Nov. 17, 2023
SIGNATURE:	<u>HUA XIE</u> NAME: HUA XIE POSITION: GENERAL MANAGER