AOJ MEDICAL Shenzhen AOJ Medical Technology Co., Ltd

This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device covered by the present Declaration is in conformity with all regulations or directives below, including compliance with related Essential Requirements and General Safety and Performance Requirements.

Object of the declaration

Product Name	Infrared Thermometer
Model Number	AOJ-20A
Product Type	Medical Thermometer
Intended Purpose	The digital thermometer provides a quick and highly accurate reading of an individual's body temperature.
Product Descriptions	The digital thermometer is intended to measure the human body's temperature in regular mode orally, rectally or under the arm, and the device is reusable for clinical or home use on people of all ages.
Basic UDI-DI	697204011AOJ25X17Z
Control Indicator	Lot number

The object of the Declaration described above is in conformity with the following regulations:

EU Directive	**Medical Device Directive (93/42/EEC as amended by 2007/47/EC)**
Device Risk Classification	Class IIa based on Annex V
Conformity Assessment Path	Annex IX Conformity assessment based on a quality management system and on assessment of technical documentation
Notified Body Name, Address, and ID	**NB Name:** TÜV SÜD Product Service GmbH **Address:** Ridlerstraße 65, 80339 MÜNCHEN, Germany **NB Code:** 0123
Certificate(s) issued	**G2 1037030001 Rev.00**
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. ISO 14155:2020, ISO 14971:2019, IEC 60601-1:2005,AMD:2012, IEC 60601-1-11:2015 for use in conjunction with IEC 60601-1:2005,AMD:2012,ISO 80601-2-56:2017,AMD1:2018 for use in conjunction with IEC 60601-1:2005.COR1:2006,COR2:2007,AMD1:2012,IEC 60601-1-2:2014,EN 60601-1-2:2015.IEC 60601-1-11:2015 clause 12, EN 60601-1-11:2015 clause 12, ISO 80601-2-56:2017+A1:2018 clause 201.17&202, EN ISO 80601-2-56:2017+A1:2020 clause 201.17&202, ISO 10993-5:2009,ISO 10993-10:2010,

EU Directive	**Directive 2011/65/EU of the European Parliament and of the Council of 08 June 2011 on the restrictions of the use of certain hazardous substances in electrical and electronic equipment, amended up to and inclusive of Directive (EU) 2015/863 (RoHS)**
Device Classification	Category 8, medical device, according to Annex I

Address: Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. IEC 62474:2012, IEC 62321:2013, EN 62321:2009, EN 50581:2012, IEC/TR62476

Additional information

Manufacturer	**Name:** Shenzhen AOJ Medical Technology Co., Ltd. **Address:** Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126, Shenzhen, China **SRN:**CN-MF-000018386
EU Authorized Representative	**Name:** Share Info GmbH **Address:** Heerdter Lohweg 83, 40549 Düsseldorf, Germany. **SRN:** DE-AR-000005132
Quality Certificates Issued	The Manufacturer is certified by TUV to the following: EN ISO 13485:2016 , as evidenced by certificate number Q5 103703 0004 Rev.01

Signature (signed for and on behalf of Shenzhen AOJ Medical Technology Co., Ltd.)

Date of Issue: 2024.04.30

Printed Name: Wendy Lin

Title: Sales Director

Place of Issue: Shenzhen