Declaration of Conformity

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.

1. Object of the declaration:

Product Name	Infrared Thermometer
Model Number	AOJ-20A, AOJ-20B, AOJ-20C, AOJ-20D, AOJ-20E, AOJ-20F, AOJ-20H, AOJ-20M, AOJ-20T,AOJ-20Y,AOJ-20R
Product Type	Thermometer
Intended Purpose	The infrared thermometers take human body temperature via the eardrum or forehead. The forehead mode is indicated for people of all ages and the eardrum mode is indicated for people above three months old. It applies to both professional use and home use.
Product Descriptions	The infrared thermometer is a handheld device that displays the temperature of the measured object by measuring the thermal radiation of the eardrum or forehead.Measurement unit:℃ or ℉.
Basic UDI-DI	697204011AOJ20X178
Control Indicator	Lot number
Global Medical Device Nomenclature Code (GMDN) and Description or EMDN Code and Description	GMDN code: 63711 Infrared patient thermometer,ear/skin EMDN Code:V03010199 THERMOMETERS - OTHER

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

EU Regulation	**Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 on medical devices (EU MDR)**
Device Risk Classification	Class IIa based on Rule 10 in Annex VIII
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	NO. G10 103703 0006
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. EN 60601-1:2006/A2:2021,EN 60601-1-11:2015 /A1: 2021, EN 60601-1-2:2015/A1:2021, EN ISO 80601-2-56: 2017/A1:2020, EN ISO 14155:2020,

	EN ISO 14971: 2019/A11:2021, EN 60601-1-6:2010/A2:2021, EN 62366-1:2015 /A1:2020, EN 62304: 2006/A1:2015, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-23: 2021, ISO 15223-1:2021

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) 2017/2102 (RoHS)**
Device Classification	Category 8, medical device, according to Annex I
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. EN 62321-3-1:2014,EN 62321-5:2014,EN 62321-7-1:2015,EN 62321-7-2:2017,EN 62321-6:2015,EN 62321-8:2017

EU Directive	**Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment (RED)**
Conformity Assessment Path	Annex II Module A
Standards	The radio equipment was tested to the following standards or technical specifications: ETSI EN 300 328 V2.2.2 (2019-07) ETSI EN 301 489-1 V2.2.3 (2019-11) ETSI EN 301 489-17 V3.2.4 (2020-09) EN 62368-1:2014+A11:2017 EN 62368-1: 2020+A11:2020 EN 50663:2017 EN 62479:2010

2. 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, PEOPLE'S REPUBLIC OF 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

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

Date of Issue:
2023.10.16

Printed Name: Jerry Gao

Place of Issue: Shenzhen

Title: Person Responsible for Regulatory Compliance