奥极医疗
AOJ MEDICAL

Pulse Oximeter EU Declaration of Conformity

Document No：CE-AOJ-70X-TD-07

Revision History:

Revision	Date	Change Description	Draft by	Reviewed by	Approved by
A0	2021-09-21	Initial release	Baiyu Xie	Jerry Gao	Jerry Gao
A1	2025-07-17	Update product information	Kexin Chen	Jerry Gao	Jerry Gao

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	Pulse Oximeter
Model Number	AOJ-70A, AOJ-70B, AOJ-70C,AOJ-70D, AOJ-70E,OXI-70E
Product Type	Pulse Oximeter
Intended Purpose	The pulse oximeter is a reusable device and intended for spot-checking of oxygen saturation and pulse rate for use with the finger of adult patients in healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.
Product Description	SpO_2 stands for peripheral capillary oxygen saturation. Oxygen saturation is defined as the ratio of oxyhemoglobin (HbO_2) to the total concentration of hemoglobin (i.e. Oxyhemoglobin + reduced hemoglobin) present in the blood. It is an important physiological parameter involved in respiration and circulation. The Pulse Oximeter feature herein is small, portable, non-invasive and easy to use. The user only needs to insert a finger into the chamber to measure his/her SpO_2 and pulse rate. The oximeter is suitable for home healthcare environments.
Basic UDI-DI	697204011AOJ70X18B
Control Indicator	Lot number
Global Medical Device Nomenclature Code (GMDN) and Description or EMDN Code and Description	GMDN code: 45607 Pulse oximeter, battery-powered EMDN code: Z1203020408 PULSE OXIMETERS

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 81060-2-61:2019,EN 14155:2020, EN ISO 14971: 2019/A11:2021 , IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 , IEC 62304:2006/A1:2015, IEC 62366-1:2015+AMD1:2020, ISO 10993-1:2018, ISO 10993-10:2021, ISO 10993-5:2009, ISO 10993-23:2021, EN 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 62321-7-1:2015,EN 62321-6:2015,EN 62321-8:2017

EU Directive	**Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), as amended.**
Conformity Assessment Path	Communication on Substances of Very High Concern (SVHCs) present above 0.1% (w/w) in the product.

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 50663:2017 EN 62479:2010

2. Additional information:

Manufacturer	**Name:** Shenzhen AOJ Medical Technology Co., Ltd. **Address:** Room 301&4-5F, 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:** Am Schulzentrum 12,41564 Kaarst, 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: 2025.12.09

Printed Name:Jerry Gao Jerry Gao

Place of Issue: Shenzhen

Title: Person Responsible for Regulatory Compliance