奥极医疗
AOJ MEDICAL

深圳市奥极医疗科技有限公司
Shenzhen AOJ Medical Technology Co., Ltd

EU 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	Arm Blood Pressure Monitor
Model Number	AOJ-30A, AOJ-30B, AOJ-30C, AOJ-30D, AOJ-30E, AOJ-30F, AOJ-30G, AOJ-33A, AOJ-33B
Product Type	Blood pressure monitor
Intended Purpose	The Arm Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home.
Product Descriptions	The proposed device, AOJ-30 Series Electronic Blood Pressure Monitor, is a battery driven automatic on-invasive blood pressure monitor. It can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult person at upper arm within its claimed range and accuracy via the oscillometric technique. User can select the unit of the measurement: mmHg or kPa.
Basic UDI-DI	697204011AOJ30X17F
Control Indicator	Lot number
Global Medical Device Nomenclature Code (GMDN) and Description or CND Code and Description	GMDN code: 45617 Automatic-inflation electronic sphygmomanometer, portable, arm/wrist CND Code: Z1203020302 non–invasive blood pressure monitoring instruments

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 m edical 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 ISO 14155:2020, EN 60601-1:2006/A1:2013, EN 60601-1-11:2015, EN ISO 81060-1: 2012, EN ISO 81060-2: 2019, EN IEC 60601-1-2:2015, IEC 80601-2-30:2018, EN ISO 14971:2012, IEC 60601-1-6: 2010/A1:2013, IEC 62304:2006/A1:2015, IEC 62366-1:2015, ISO 10993-1:2018, ISO 10993-10:2010, ISO 10993-5:2009, 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. IEC 62474:2012, IEC 62321:2013, EN 62321:2009, EN 50581:2012, IEC/TR62476

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 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

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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

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

Jerry Gao

Printed Name: Jerry Gao

Date of Issue:

2022.10.20

Place of Issue: Shenzhen

Title: Person Responsible for Regulatory Compliance