JIANGSU YUYUE MEDCIAL EQUIPMENT & SUPPLY CO., LTD.

Declaration of Conformity

Revision History

No.	Version	Reviser	Revised Sections and Content	Revision Date
1	A/0	Yuhua Li	First release	2022.10.18
2	A/1	Jiabin Sun	Update	2023.10.08
3	A/2	Jiabin Sun	Update" (EC) Certificate(s)" and " Expire date of the Certificate"	2024.03.05
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Prepared by: Jiabin Sun Reviewed by: Lei Zhao Approved by:

Date: 2024.03.05 Date: 2024.03.05 Date: 2024.03.05

Declaration of Conformity

Manufacturer: Name:JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.
Address: No.1 Baisheng Road Development Zone,Danyang,Jiangsu 212300 CHINA
SRN：CN-MF-000012834

European Representative:
Name: Metrax GmbH
Address: Rheinwaldstr. 22, D-78628 Rottweil, Germany
SRN：DE-AR-000005481

Product Category	Finger Pulse Oximeter
Model	YX105, YX106
Intended purpose	The Finger Pulse Oximeter is a kind of non-invasive device which can measure and display SpO_2 and pulse rate. It is intended for adults and children and is expected for home and hospital inspection.
UMDNS Code	17148
Classification	IIa based on MDR 2017/745 annex VIII rule 10
Basic UDI-DI	69332S792317J4
Conformity Assessment Route	MDR Annex IX chapter I, chapter III and Section 4

We declare that above mentioned products meet the provision of the following EC Council Directive and Regulation. All the supporting documents and files are retained under the premises of the manufacture. We are exclusively responsible for the Declaration of Conformity. There is no applicable common specifications for Finger Pulse Oximeter.

General applicable directives and regulation:

Medical Device Regulation (EU) 2017/745

RoHS Directive 2011/65/EU Annex II and its amendment (EU) 2015/863

WEEE Directive 2012/96/EU

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr.65, 80339München, Germany

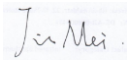
Notified Body Number: 0123

(EC) Certificate(s): 2024.03.04

Expire date of the Certificate: 2029.03.03

Start of CE Marking: Not Yet

Place, Date of Issue: DanYang, Jiangsu, P.R.CHINA

Signature: 

Name: Jie Mei

Position: **Person Responsible for Regulatory Compliance.**

List of EU harmonized and international standards

S/N	Ref. No.	Title
1	MDR 2017/745	Medical Device Directives of EU
2	EN ISO 13485:2016/A11:2021	Medical devices-Quality management systems-Requirements for regulatory purposes
3	EN ISO 14971:2019/A11:2021	Medical devices-Application of risk management to medical devices
4	EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
5	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
6	ISO 780:2015	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages
7	IEC 60601-1:2005+AMD1:2012+AMD2:2020	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
8	IEC 60601-1-2:2014+AMD1:2020	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests
9	ISO 80601-2-61:2017, COR1:2018	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
10	IEC 60601-1-11:2015+AMD1:2020	Medical electrical equipment –Part 1- 11: General requirements for basic safety and essential performance –Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
11	IEC 60601-1-6:2010+AMD1:2013+AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
12	IEC 62366-1: 2015/AMD:2020	Medical devices - Part 1: Application of usability engineering to medical devices
13	IEC TR 62366-2: 2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices
14	IEC 62304:2006/AMD1:2015	Medical device software — Software life cycle
15	IEC 60601-1-6:2010+AMD1:2013+AMD2:2020	Medical devices - Part 1: Application of usability engineering to medical devices
16	ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
17	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
18	ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization

19	MEDDEV 2.7.1 Rev. 4	Clinical evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
20	ISO TR 24971:2020	Medical devices - Guidance on the application of ISO 14971
21	ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation