

Declaration of Conformity to MDR 2017/745 concerning Medical Devices

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| Manufacturer: | Beijing Choice Electronic Technology Co., Ltd. 2nd Floor, 3rd Floor and Room 410-412 4th Floor, No. 2 Building, No. 9 Shuangyuan Road, Shijingshan District, 100041 Beijing, PEOPLE'S REPUBLIC OF CHINA SRN: CN-MF-000005776 Tel: +86-10-88203956 Fax: +86-10-88204632 E-mail: cc@choicemmed.com |
| European Representative: | Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany Tel: +49-40-2513175 Fax: +49-40-255726 E-mail: shholding@hotmail.com |
| Product: | Pulse Oximeter |
| Model: | MD300C2, MD300C22, MD300C23, MD300C26, MD300C29, MD300C21, MD300C203, MD300C208, MD300C228, OXY300, MD300C298 |
| Basic UDI-DI: | 69428204SPO2VG |
| UMDNS Code: | 17148 |
| Classification: | Class IIa, rule 10 to Annex VIII of MDR 2017/745 |
| Conformity assessment Route: | Annex IX chapter I, chapter III, and section.4 |

We, the manufacturer, herewith declare that the stated medical devices meet the transposition into national law, the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

All supporting documentation is retained at the premises of the manufacturer.

We, the manufacturer, are sole responsible for the DoC.

Standards applied:

EN ISO 13485:2016/A11:2021 Medical devices- Quality management systems- Requirements for regulatory purposes

EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices

IEC 60601-1: 2005+A1:2012+A2:2020 Medical electrical equipment-Part 1: General requirements for

safety

IEC 60601-1-2: 2020 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60601-1-11: 2015+A1:2020 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

EN ISO 80601-2-61:2019 Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

EN 60601-1-6:2010+A2-2021 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

EN 62304-2006+A1-2015 Medical device software-Software life-cycle processes

EN ISO 10993-1-2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EN ISO 20417:2021 Medical devices - Information supplied by the manufacture

EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Notified Body: TÜV SÜD Product service GmbH
Ridlerstr 65, D-80339 München, Germany

Identification Number: 0123

(EC) Certificate(s): No. G10 057571 0008 Rev.00

Start of CE-marking: 2023-05-19

Place, Date of Declaration: Beijing, 2023-05-19

Signature: 

Name: Haiying Zhao

Position: Quality Director