| globalcare 中山市全康医疗科技有限公司 | EC Declaration of Conformity | F-REG-002 Rev.00 20200110 |
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| MANUFACTURER: | Globalcare Medical Technology CO., LTD.<br>7th Building, 39 Middle Industrial Main Road,EuropeanIndustrial Zone,<br>Xiaolan Town, 528415 Zhongshan City,Guangdong Province,<br>PEOPLE'S REPUBLIC OF CHINA |
| Single registration number (SRN): | CN-MF-000033595 |
| Product Category: | Z12030205-NON INVASIVE BLOOD PRESSURE MONITORS |
| Product Type: | GCE609 |
| Product Description: | Veroval BPU 26 |
| Basic UDI-DI: | 697022925GCE6XXEB |
| Classification - Annex VIII: | Class IIa, Rule 10 |
| Conformity Assessment Route: | ANNEX IX Chapters I and III |

We, the manufacturer, herewith declare that the stated medical device meets the provisions of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
All supporting documentation is retained at the premises of the manufacturer.
Globalcare Medical Technology CO., LTD. is exclusively responsible for this EC Declaration of Conformity.

Standards Applied: See attached list

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| Notified body: | |
| Name: | TÜV SÜD Product Service GmbH<br>Certification Body |
| Address: | Ridlerstraße 65<br>80339 Munich, Germany |
| Identification Number | 0123 |
| (EC) Certificate(s): | G10 088855 0016 Rev. 00 |
| EC REP<br>European Representative: | Donawa Lifescience<br>Piazza Albania, 10<br>00153 Rome<br>Italy |

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| Place, Date of Declaration: | Zhongshan, 2023-4-6 |
| Signature: | Name:Lambert Zhao<br>Position: General Manager |

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| Product Category | Blood pressure measuring equipment |
| Product Family | GCE609 product family |

| Reference | Title |
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| Regulation(EU) 2017/745 | Medical Device Regulation |
| IEC60601-1:2005/A2:2020<br>EN 60601-1:2006/A2:2021 | Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2:2014+AMD1:2020<br>EN 60601-1-2:2015+A1:2021 | Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests |
| EN 60601-1-6: 2010/A2:2021 | Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability. |
| IEC 60601-1-11:2015/A1 :2020<br>EN 60601-1-11:2015/A1 :2021 | 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. |
| ISO 14971:2019<br>EN ISO14971:2019/A11:2021 | Medical devices - Application of risk management to medical devices. |
| IEC 80601-2-30: 2018<br>EN 80601-2-30 :2019 | Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers |
| ISO 81060-2:2013 | Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type |
| EN ISO 20417:2021 | Medical devices — Information to be supplied by the manufacturer |
| 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. |
| ISO 10993-1 :2018<br>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. |
| EN ISO 10993-10:2013 | Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization. |
| ISO 13485:2016<br>EN ISO 13485:2016/A11:2021 | Medical devices - Quality management systems - Requirements for regulatory purposes |
| Dir. 2011/65/EU (RoHS) | Restriction of the use of certain hazardous substances in electrical and electronic equipment. |
| Reg. 1907/2006/EU (REACH) | Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency |
| Dir. 2012/19/EU | Waste electrical and electronic equipment |
| IEC 62304:2006/A1: 2015 | Medical device software - Software life-cycle processes |
| EN 62366-1: 2015/A1:2020 | Medical devices - Application of usability engineering to medical devices. |

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| 2014/53/EU | The Radio Equipment Directive, RED |
| ISTA-2A | ISTA 2 Series Partial Simulation Performance Test Procedure:Packaged-Products 1 50 lb (68 kg) or Less |

| STATE | FUNCTION | DATE | SIGNATURE |
|---|---|---|---|
| ISSUED: **Yoyo Zhang** | **Regulatory specilist** | April 6, 2023 | Yoyo Zhang |
| APPROVED: **Janice Deng** | **Regulatory and compliance Officer** | April 6, 2023 | Janice Deng |