EU DECLARATION OF CONFORMITY

Doc. No./Rev : Ber-DC-040/A1 **No. : BER-CE-DT-028**

Manufacturer Guangzhou Berrcom Medical Device Co., Ltd.
No.38 Huanzhen Xi Road, Dagang Town, Nansha, 511470 Guangzhou, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Single Registration Number (SRN): CN-MF-000013852

Authorized Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80,20537, Hamburg, Germany.

SRN Authorized Representative: DE-AR-000000001

Product Identification

Product/Trade Name: Digital Thermometer/Hartmann
Model: DT116, DT119
Reference/Catalogue number: Thermoval flex, Thermoval rapid

Basic UDI-DI: 69476561DTXXX4R

Intended use: Digital Thermometer is intended for the measurement of human body temperature by doctors or customers in the hospital or at home. It can be used for axillary, oral and rectal temperature measurement. The product is reusable and provided nonsterile. The device is intended for use on people of all ages.

Product Code

GMDN Code: 14035
GMDN Term: Intermittent electronic patient thermometer
EMDN Code: V0301010201
EMDN Term: CONTACT DIGITAL THERMOMETERS

Classification

Risk Class: Class IIa
(According to rule 10 of Annex VIII Medical Device Regulation (EU) 2017/745)

Applied Standards: Refer to Annex 1

Conformity assessment Route: Annex IX Chapters I and chapter III of Regulation (EU) 2017/745

We (Guangzhou Berrcom Medical Device Co., Ltd) declare that the above medical device is at our sole responsibility the state medical device digital thermometer in conformity with the following legislation(s):

Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices

The conformity of the quality management system according to Annex IX and Article 52 is certified by the following notified body:

TÜV SÜD Product service GmbH
Ridlerstr 65, 80339 München, Germany

The identification number of the notified body for implementation of the procedure set out in Annex IX and Article 52 to the above regulation is: 0123 CE 0123

Certificate number of issued certificate: G10 082883 0017 Rev. 00
Reference to Common Specifications: NA

This declaration of conformity is issued under the sole responsibility of Guangzhou Berrcom Medical Device Co., Ltd.

This declaration supersedes any declaration issued previously for the same product.

Place and date *<Guangzhou, China, Mar. 25, 2025>*

Signature

Name Zhigang Du

Position Person Responsible for Regulatory Compliance

Signature

Name Zhichao Guo

Position General Manager

Annex 1 Applied Standards

EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971: 2019	Information supplied by the manufacturer of medical devices
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirements
EN 62304:2006+A1:2015	Medical device software - Software life-cycle processes
EN 60601-1-6:2010+A1+A2:2021	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366-1:2015+A1:2020	Medical devices - Application of usability engineering to medical devices
EN 60601-1:2006/A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-11:2015/A1:2021	Medical electrical equipment — Part 1-11: eneral 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 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 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 10993-10:2023	Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
EN ISO 10993-23:2021	Biological evaluation of medical devices Part 23: Tests for irritation
EN ISO 80601-2-56:2017/A1:2020	Medical electrical equipment. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
Regulation (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, amended Directive 2001/83/EC
2011/65/EU (RoHS)	on the restriction of the use of certain hazardous substances in electrical and electronic equipment
1907/2006/EU (REACH)	concerning the Registration,Evaluation, Authorisation and Restriction of Chemicals (REACH)