



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-099



Product Service

## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 088855 0016 Rev. 00**

**Manufacturer:** **Globalcare Medical Technology Co., Ltd.**

7th Building  
39 Middle Industrial Main Road  
European Industrial Zone, Xiaolan Town  
528415 Zhongshan City, Guangdong Province  
PEOPLE'S REPUBLIC OF CHINA

**SRN Manufacturer:** Not available at issuance date of this certificate

**Authorized Representative:**

Donawa Lifescience Consulting Srl  
Piazza Albania, 10, 00153 Rome, ITALY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10\\_088855\\_0016\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:G10_088855_0016_Rev.00)

**Report No.:** GZ2019503

**Valid from:** 2021-10-29

**Valid until:** 2026-10-28

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2021-10-29



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**No. G10 088855 0016 Rev. 00**

**Classification:** IIa  
**Device Group:** Z12159002 - AEROSOL GENERATORS  
**Intended Purpose:** /

**Classification:** IIa  
**Device Group:** Z12030205 - NON INVASIVE BLOOD PRESSURE MONITORS  
**Intended Purpose:** /

**Classification:** IIa  
**Device Group:** Z12080303 - BREAST PUMPS  
**Intended Purpose:** /

**Classification:** IIa  
**Device Group:** Z12040299 - GENERAL MEDICINE INSTRUMENTS FOR THERAPEUTIC TREATMENTS - OTHERS  
**Intended Purpose:** /

**Classification:** IIa  
**Device Group:** V03010102 - ELECTRONIC THERMOMETERS AND END CAPPS  
**Intended Purpose:** /

**Classification:** IIa  
**Device Group:** Z12050403 - ECG HOLTER RECORDERS  
**Intended Purpose:** /

**Classification:** IIa  
**Device Group:** Z12030202 - MULTI-PARAMETER PATIENT MONITORS  
**Intended Purpose:** /

The validity of this certificate depends on conditions and/or is limited to the following: -none-