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

TÜV SÜD 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 023971 0038 Rev. 00

Manufacturer: **em-tec GmbH**
Lerchenberg 20
86923 Finning
GERMANY

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.

Report No.: 713169634

Preceding certificate No.: The certificate is issued for the first time

Valid from: 2020-03-24
Valid until: 2025-03-23

Date of initial issuance / Rev.00: 2020-03-24

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-03-24

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. G10 023971 0038 Rev. 00

Devices:	Risk Classification:	CND Code:
Extracorporeal Perfusion Pump/Oxygenator Instruments	IIb	Z120502

Intended Purpose:
The Capacitive Level Sensor (CLS) is used as an electronic sensor component for integration into electrical or electronic equipment and medical devices, referred to as base unit. The base unit must have appropriate electronics which supplies the sensor via the plug with the specified DC voltage and detects the current consumption as well as the signal voltage at the interface and processes the data accordingly. The reusable CLS is used together with the disposable Level Sensor Pad (LSP) to monitor fluid levels, for example blood or saline solutions used in a hard shell or bag reservoirs. The CLS contains the sensor electronics and outputs a change in the electrical signal when the level falls below a specified value. The monitored area is determined by the position of the LSP.

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

Revision History including Changes:

Revision / Issue Date / Report
Rev.00 / 2020-03-24/ 713169634

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