ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 014048 0027 Rev. 01

Manufacturer:

Herco Wassertechnik GmbH
Planckstraße 26
71691 Freiberg am Neckar
GERMANY

SRN Manufacturer - DE-MF-000007521

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 014048 0027 Rev. 01

Report No.: 713299902

Preceding Certificate No.: G10 014048 0027 Rev. 00

Valid from: 2024-09-18
Valid until: 2028-02-16

Date of Initial Issuance: 2023-02-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-09-18

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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Classification:	Class IIa
Device Group:	Z12099099 - VARIOUS NEPHROLOGY AND HAEMODIALYSIS INSTRUMENTS - OTHER
Intended Purpose:	./.
Classification:	Class IIb
Device Group:	Z12099007 - DIALYSIS WATER TREATMENT SYSTEMS
Intended Purpose:	The system serves as a medical device for stationary dialysis water treatment to desalinate softened, chlorine-free and filtered drinking water for the purpose of centrally supplying several dialysis stations with desalinated, largely germ-free dialysis water. The dialysis water is supplied to the dialysis stations via a closed ring main, which is not part of this plant. The dialysis water provided is also used to prepare dialysis concentrates.
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2023-02-17	713224707	-
01	2024-09-18	713299902	Supplemented: Device(s)/group of device(s) added

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