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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 064517 0011 Rev. 00

Manufacturer:

ADVITOS GmbH
Agnes-Pockels-Bogen 1
80992 München
GERMANY

SRN Manufacturer - DE-MF-000012040

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 064517 0011 Rev. 00

Report No.: 713273585

Valid from: 2024-02-29
Valid until: 2029-02-28

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-02-29

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 064517 0011 Rev. 00

Classification:	Class IIb
Device Group:	Z120902 - HAEMODIALYSIS INSTRUMENTS
Intended Purpose:	The device is part of the haemodialysis system, which is intended to remove water-soluble toxic substances, protein-bound toxic substances, to normalize or improve the composition of blood in case of e.g., electrolyte or acid-base disturbances (e.g., metabolic acidosis or respiratory acidosis) and to remove fluids in case of fluid overload.
Classification:	Class IIb
Device Group:	F040101 - DIALYSIS CONCENTRATES, ACID SOLUTIONS, NON-STERILE
Intended Purpose:	The product is part of the haemodialysis system, which is intended to remove water-soluble toxic substances, protein-bound toxic substances, to normalize or improve the composition of blood in case of e.g., electrolyte or acid-base disturbances (e.g., metabolic acidosis or respiratory acidosis) and to remove fluids in case of fluid overload.
Classification:	Class IIb
Device Group:	F040202 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, LIQUID
Intended Purpose:	The product is part of the haemodialysis system, which is intended to remove water-soluble toxic substances, protein-bound toxic substances, to normalize or improve the composition of blood in case of e.g., electrolyte or acid-base disturbances (e.g., metabolic acidosis or respiratory acidosis) and to remove fluids in case of fluid overload.
Classification:	Class IIb
Device Group:	F0499 - DIALYSIS CONCENTRATES - OTHER
Intended Purpose:	The product is part of the haemodialysis system, which is intended to remove water-soluble toxic substances, protein-bound toxic substances, to normalize or improve the composition of blood in case of e.g., electrolyte or acid-base disturbances (e.g., metabolic acidosis or respiratory acidosis) and to remove fluids in case of fluid overload.
The validity of this certificate depends on conditions and/or is limited to the following:	none

Revision History:

Rev.	Dated	Report	Description
00	2024-02-29	713273585	Initial issuance

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