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 010393 0534 Rev. 04

Manufacturer:

CODAN Medizinische Geräte GmbH
Stig Husted-Andersen Strasse 11
23738 Lensahn
GERMANY

SRN Manufacturer - DE-MF-000005286

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 010393 0534 Rev. 04

Report No.:	713311154
Preceding Certificate No.:	G10 010393 0534 Rev. 03
Valid from:	2023-12-06
Valid until:	2027-02-16
Date of Initial Issuance:	2022-02-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-12-06

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	Class IIa
Device Group:	A030101 - INFUSION CONTROLLERS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A030201 - EXTENSIONS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0399 - TUBULAR DEVICES - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A030102 - IRRIGATION CONTROLLERS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0704 - SYSTEMS FOR RECONSTITUTION AND ADMINISTRATION OF PHARMACEUTICALS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A040101 - ADMINISTRATION AND ASPIRATION FILTERS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A070101 - ASPIRATION LINES ADAPTERS AND CONNECTORS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A070103 - INFUSION LINES ADAPTERS AND CONNECTORS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0702 - RAMPS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0703 - STOPCOCKS

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No. G10 010393 0534 Rev. 04

Intended Purpose: -

Classification: Class IIa
Device Group: A070501 - CAPS OR OBTURATORS, NON-PERFORABLE
Intended Purpose: -

Classification: Class IIa
Device Group: A070502 - CAPS OR OBTURATORS, PERFORABLE
Intended Purpose: -

The validity of this certificate depends on conditions and/or is limited to the following: -

Revision History:

Rev.	Dated	Report	Description
00	2022-02-17	713213305	-
01	2023-01-02	713213305	-
02	2023-04-12	713264388	Supplemented: Device(s)/group of device(s) added
03	2023-10-19	713298954	Supplemented: Device(s)/group of device(s) added
04	2023-12-06	713311154	Supplemented: Device(s)/group of device(s) added

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