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 060815 0012 Rev. 00

Manufacturer:

CODAN pvb Critical Care GmbH
Römerstrasse 18
85661 Forstinning
GERMANY

SRN Manufacturer - DE-MF-000007510

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 060815 0012 Rev. 00

Report No.: 713264120

Valid from: 2024-01-22
Valid until: 2029-01-21

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-01-22

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 060815 0012 Rev. 00

Classification:	Class IIa
Device Group:	Z1203020301 - INVASIVE BLOOD PRESSURE MONITORING INSTRUMENTS
Intended Purpose:	-

Classification:	Class IIb
Device Group:	Z1203020301 - INVASIVE BLOOD PRESSURE MONITORING INSTRUMENTS
Intended Purpose:	The pressure monitoring set is intended for use on a patient requiring continuous monitoring of their blood pressure via one or more vascular access ports (IBPM) and/or requiring blood withdrawals.

Classification:	Class IIb
Device Group:	Z1203020301 - INVASIVE BLOOD PRESSURE MONITORING INSTRUMENTS
Intended Purpose:	The pressure monitoring set is intended for use on a patient requiring continuous monitoring of their blood pressure via one or more vascular access ports (IBPM).

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

Revision History:

Rev.	Dated	Report	Description
00	2024-01-22	713264120	Initial issuance

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