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

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 096586 0006 Rev. 00

Manufacturer:

CODAN ARGUS AG
Oberneuhofstrasse 10
6340 Baar
SWITZERLAND

SRN Manufacturer - CH-MF-000025571

Authorized Representative:

CODAN pvb Critical Care GmbH
Römerstrasse 18, 85661 Forstinning, GERMANY

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:G15 096586 0006 Rev. 00

Report No.: 713299987
Valid from: 2025-05-20
Valid until: 2030-05-19

Issue date: 2025-05-20

Christoph Dicks
Head of Certification/Notified Body

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Certificate No. G15 096586 0006 Rev. 00

Classification:	Class IIb
Device Group:	Z120303 - INFUSION INSTRUMENTS
Intended Purpose:	The intended use of the syringe pump is the continuous or intermittent delivery at precisely-controlled infusion rates of liquid medications, parenteral nutrition solutions, blood and blood products by intravenous infusion
Classification:	Class IIb
Device Group:	Z120303 - INFUSION INSTRUMENTS
Intended Purpose:	The intended use of the volumetric pump is the continuous or intermittent delivery at precisely-controlled infusion rates of liquid medications, parenteral nutrition solutions, blood and blood products by intravenous infusion
The validity of this certificate depends on conditions and/or is limited to the following:	none

Rev.	Dated	Report	Description
00	2025-05-20	713299987	Initial issuance

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