



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-099



EU Quality Management System Certificate

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

Certificate No. G15 013006 0024 Rev. 01

Manufacturer:

Arcomed AG

Steinackerstrasse 29
8302 Kloten
SWITZERLAND

SRN Manufacturer - CH-MF-000035749

**Authorized
Representative:**

Susen Akermann
An der Stalden 5, 78337 Öhningen, 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 (excluding custom-made implantable devices) 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 013006 0024 Rev. 01

Report No.: 713309090 / 713311633

Preceding Certificate No.: G15 013006 0024 Rev. 00

Valid from: 2026-07-30

Valid until: 2031-07-08

Date of Initial Issuance: 2026-07-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-07-30



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Classification:	Class IIb
Device Group:	Z12030301 - INFUSION PUMPS
Intended Purpose:	The Volumed Infusion Pump is a pressure infusion device intended to facilitate a controlled administration of infusate such as pharmaceutical drugs from a fluid bag, through an infusion tube and into a patient's body using a peristaltic mechanism. Alternatively to pharmaceutical drugs, also nutrition solutions can be administered to the patient.

Classification:	Class IIb
Device Group:	Z12030302 - SYRINGE PUMPS
Intended Purpose:	The Syramed Infusion Pump is a pressure infusion device intended to facilitate a controlled administration of infusate such as pharmaceutical drugs from a pre-filled Syringe and into a patient's body using a controlled single action pumping stroke.

The validity of this certificate depends on conditions and/or is limited to the following:	none
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Revision History:

Rev.	Dated	Report	Description
00	2026-07-09	713309090 / 713311633	Initial issuance
01	2026-07-30	713309090 / 713311633	Amended: Change of authorized representative's data