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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 126408 0003 Rev. 01

Manufacturer:

Control-X Medical Zrt

Röntgen u. 6
2120 Dunakeszi
HUNGARY

SRN Manufacturer - HU-MF-000008177

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 126408 0003 Rev. 01

Report No.: 713418156

Preceding Certificate No.: G15 126408 0003 Rev. 00

Valid from: 2026-10-12

Valid until: 2030-12-01

Date of Initial Issuance: 2025-12-02

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2026-10-12



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Certificate No. G15 126408 0003 Rev. 01

Classification:

Class IIb

Device Group:

Z110311 - DIRECT DIGITAL RADIOLOGY (DR) SYSTEMS

Intended Purpose:

The radiographic system is intended for performing digital radiographic diagnostic procedures of the human anatomy. The system enables medical personnel to perform general radiographic examinations (e.g., chest, abdomen, extremities) on adult and pediatric patients in clinical environments.

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

Revision History:

Rev.	Dated	Report	Description
00	2025-12-02	713347588	Initial issuance
01	2026-10-12	713418156	Supplemented: Change to the approved type(s)/device(s)