



EU Quality Management System Certificate

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

Certificate No. G15 024169 0060 Rev. 00

Manufacturer: EUROSETS S.R.L.

Strada Statale 12, 143
41036 Medolla (MO)
ITALY

SRN Manufacturer - IT-MF-000023171

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 024169 0060 Rev. 00

Report No.: ITA200220015002
Preceding Certificate No.: G12 024169 0053 Rev. 00

Valid from: 2026-03-09
Valid until: 2027-09-29

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-03-09



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Classification: Class III
Device Group: MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools
Intended Purpose: See product certificate

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

Revision History:

Rev.	Dated	Report	Description
00	2026-03-09	ITA200220015002	Supplemented: Device(s)/group of device(s) added