



EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 024169 0059 Rev. 00

Manufacturer:

EUROSETS S.R.L.

Strada Statale 12, 143
41036 Medolla (MO)
ITALY

SRN Manufacturer - IT-MF-000023171

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation 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 technical documentation assessment included an assessment of the clinical evaluation assessment.

The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.

In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapter I is necessary in addition to this EU Technical Documentation Assessment Certificate. 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:G70 024169 0059 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G70_024169_0059_Rev.00)

Report No.: 713279465

Valid from: 2026-03-12

Valid until: 2031-03-11

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-03-12



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



Product Service

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 (Implantable Class IIb Devices and Class III Devices)

No. G70 024169 0059 Rev. 00

Classification: Class III
Basic UDI-DI: 805270549EUSE-30-730Y8
Intended Purpose: Venous cannula intended for Minimally Invasive Cardiac Surgery
 (MICS) in cardiopulmonary bypass procedure.
Device(s): FLEXDRAIN

Medical device name	Article number of the Device	Device Basic UDI-DI
FLEXDRAIN	EUSE-24-680	805270549EUSE-30-730Y8
FLEXDRAIN	EUSE-24-730	805270549EUSE-30-730Y8

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

Revision History:

Rev.	Dated	Report	Description
00	2026-03-12	713279465	Initial issuance