Certificate BE25/00000193

The management system of

ECM Europe BV

Oost- Om 54, 5422 VZ Gemert, The Netherlands

has been assessed and certified as meeting the requirements of

ISO 13485:2016/EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes

For the following activities

Design and development, manufacture, sales and distribution of Medical Tubing Sets and Systems and associated components for the purpose of extracorporeal blood circulation, enabling monitoring and transportation. Contract assembly, packaging and distribution of (sterile) medical devices concerning:

- Medical Tubing Systems (MTS)
- ExtraCorporeal Circuit System Packs
- Systems for Fluids Heating
- Irrigation sets
- Components for ophthalmic surgery
- Components for Perfusion Devices
- Components and tubings for Infusion Pumps
- Drainage and Collecting Fluids Devices
- Fluids Collection Bags and Systems

This certificate is valid from 01 September 2026 until 01 September 2029 and remains valid subject to satisfactory surveillance audits.
Issue 2. Organization certified since 01 September 2011 and first certified by SGS on 10 July 2025.

Authorised by
Pieter Weterings
Certification Manager

SGS BELGIUM NV
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

Accreditation Number
005-QMS
EN ISO/IEC 17021-1:2015

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