

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**

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 10 July 2025 until 01 September 2026 and remains valid subject to satisfactory surveillance audits.

Issue 1. 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](http://www.sgs.com)



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

