

CERTIFICATE

Number: 2144240

The management system of:

ECM Europe BV

Oost-Om 54
5422 VZ Gemert
The Netherlands

including the implementation meets the requirements of the standard:

ISO 13485:2016
EN ISO 13485:2016

Scope:

Design, manufacture and distribution of Medical Tubing Systems and associated accessories for the purpose of extra-corporeal blood circulation, monitoring and transportation.

Design, manufacture and distribution of swabs for nasopharyngeal sample collection.

Contract assembly, packaging and distribution of (sterile) medical devices concerning:

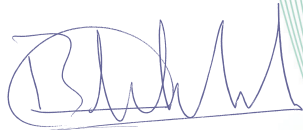
- Medical Tubing Systems
- Systems for Fluids Heating
- Irrigation sets
- Accessories for ophthalmic surgery
- Accessories for Perfusion Devices
- Accessories and tubings for Infusion Pumps
- Dental and Cranio Maxillo Facial Implants and Accessories
- Cardiac pacing wires and pacing wire patient cables
- Drainage and Collecting Fluids Devices
- Fluids Collection Bags and Systems
- Sample Collection Swabs

Certificate expiry date: 1 September 2026

Certificate effective date: 1 September 2023

Certified since: 1 September 2011

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Certification Manager

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