

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.

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

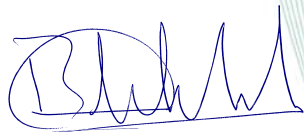
- Medical Tubing Systems
- Systems for Fluids Heating
- Irrigation sets
- Accessories for ophthalmic surgery
- Accessories for Perfusion Devices
- Accessories and tubings for Infusion Pumps
- Dental and Cranio Maxillo Facial Implants and Accessories
- Cardiac pacing wires and pacing wire patient cables
- Examination gloves
- Accessories for Hemodialysis water purification systems
- Blood Filters
- Blood Transfer Bags
- Needles
- Syringes
- Vascular introducers
- Drainage and Collecting Fluids Devices
- Fluids Collection Bags and Systems
- Sample Collection Swabs

Certificate expiry date: 1 September 2023

Certificate effective date: 1 March 2021

Certified since: 1 September 2011

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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