Certificate of Registration of Quality Management System to ISO 13485:2016

Canada - Medical Devices Regulations – Part 1- SOR 98/282
United States - 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,
☒ 21 CFR 820 - Quality System Regulation

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

MAR COR Purification
a Cantel Medical Company
14550 28th Avenue North
Minneapolis, MN 55447
USA
Facility ID: F001025

has been assessed and deemed to comply with the requirements of the above standard and regulations in respect of the scope of operations given below:

Design, Manufacturing, Installation and Service of Solution Delivery Systems and Reverse Osmosis Systems used in Hemodialysis and Distribution of Filter Products and Cleaners/Sterilants used in Hemodialysis including Dispensing Equipment.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.4437)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Certificate Number: MP19.4437 / Rev 2
Certification Granted: 2018/06/17
Effective Date: 2021/06/17
Expiry Date: 2022/06/16

Annex to Certificate Number: MP19.4437/ Rev 2

Scope of Registration:

Design, Manufacturing, Installation and Service of Solution Delivery Systems and Reverse Osmosis Systems used in Hemodialysis and Distribution of Filter Products and Cleaners/Sterilants used in Hemodialysis including Dispensing Equipment.

Activity	Location
Headquarters, Management, Design, Manufacturing, Service	MAR COR Purification a Cantel Medical Company 14550 28th Avenue North Minneapolis, MN 55447 USA File No.: MP19.4437 Facility ID: F001025
Manufacturing, Distribution, Warehouse	MAR COR Purification a Cantel Medical Company 17300 Medina Road Suite 500 Plymouth, MN 55447 USA File No.: MP19.4437/A Facility ID: F001025

Verified by:
Operations Manager