

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that: Crosstex International 6789 W. Henrietta Road Rush, NY 14543 USA

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

The Design, Manufacture, and Distribution of Sterilization Monitoring and Assurance Products, Including Chemical Indicators, Chemical Integrators, Biological Indicators, Sterilization Packaging. The Provision of Sterilizer Monitoring Services, Face Masks, Non-Sterile Single-Use Barrier Products, Dental Waterline Treatment Products and Dental Suction Devices. The Distribution of Prophy Angles, Prophy Paste, Examination Gloves, Dental Dams, Gauze, Sponges, Fluoride Trays, Fluoride Varnish and Dental Treatment Accessories.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4985)

Approved by: Kevin Mullaney Director of Certification



Registration Number: MD19.4985 — Certification Granted: June 29, 2016 Effective Date: August 08, 2023 Expiry Date: April 06, 2026





Annex to Certificate Number: MD19.4985

Scope of Registration:

The Design, Manufacture, and Distribution of Sterilization Monitoring and Assurance Products, Including Chemical Indicators, Chemical Integrators, Biological Indicators, Sterilization Packaging. The Provision of Sterilizer Monitoring Services, Face Masks, Non-Sterile Single-Use Barrier Products, Dental Waterline Treatment Products and Dental Suction Devices. The Distribution of Prophy Angles, Prophy Paste, Examination Gloves, Dental Dams, Gauze, Sponges, Fluoride Trays, Fluoride Varnish and Dental Treatment Accessories.

Activity

Administration, Design, Manufacturing, Distribution

Location

Crosstex International 6789 W. Henrietta Road Rush, NY 14543 USA

File No.: MD