



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 Prophylaxis Angles, Prophylaxis 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.: MD19.4985

Distribution

Crosstex International
1600 Marketplace Drive
Henrietta, NY 14623
USA
File No.: MD19.4985/B

Manufacturing

Crosstex International
534 Vine Street
Sharon, PA 16146
USA
File No.: MD19.4985/C

Verified by:
Director of Certification