



NSAI

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

Australia - Therapeutic Goods (Medical Devices) Regulations, 2002,

Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure.

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:

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

Facility ID: F004894

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:

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, Dental Articulating Paper/Foil/Film, Dental Matrix Strips, Dental Imaging Comfort, Tongue Depressors, Dental Cups and Mixing Pads.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.4985)

Approved by:
Geraldine Larkin
Chief Executive Officer

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

Certificate Number: MP19.4985 / Rev 3

Certification Granted: 2020/04/07

Effective Date: 2021/11/16

Expiry Date: 2023/04/06



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412

All valid certifications are listed on NSAI's website – www.nsaiinc.com The continued validity of this certificate may be verified under "Approved Client Listing"



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Annex to Certificate Number: MP19.4985 / Rev 3

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, Dental Articulating Paper/Foil/Film, Dental Matrix Strips, Dental Imaging Comfort, Tongue Depressors, Dental Cups and Mixing Pads.

Activity

Location

Administration, Design,
Manufacturing, Distribution

Crosstex International
6789 W. Henrietta Road
Rush, NY 14543
USA
Facility ID: F004894
File No.: MP19.4985

Manufacturing

Crosstex International
31 Water Street
Cuba, NY 14727
USA
Facility ID: F004894
File No.: MP19.4985/A

Distribution

Crosstex International
1600 Marketplace Drive
Henriette, NY 14623
USA
Facility ID: F004894
File No.: MP19.4985/B

Manufacturing

Crosstex International
534 Vine Street
Sharon, PA 16146
USA
Facility ID: F002309
File No.: MP19.4985/C

**Verified by:
Operations Manager**