

# 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

**Japan** - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable)

**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:

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**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:  
Kevin Mullaney  
Director of Certification

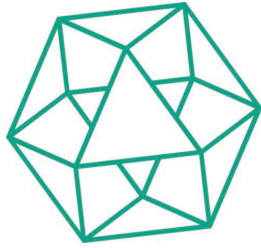
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Certificate Number: MP19.4985 / Rev 1  
Certification Granted: 2020/04/07  
Effective Date: 2023/04/07  
Expiry Date: 2026/04/06



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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](http://www.nsaiinc.com) The continued validity of this certificate may be verified under "Approved Client Listing"



# NSAI

## **Annex to Certificate Number: MP19.4985 / Rev 1**

### **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, 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  
Henrietta, 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:  
Director of Certification**