



# NSAI

## Certificate of Registration of Quality Management System to 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:

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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 and Dental Treatment Accessories. Additional sites covered under this multi-site certification are listed on the Annex (File No. CM19.4985)**

Approved by:  
Geraldine Larkin  
Chief Executive Officer

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

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Registration Number: CM19.4985  
Certification Granted: June 29, 2016  
Effective Date: November 16, 2021  
Expiry Date: April 06, 2023



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# NSAI

## Annex to Certificate Number: CM19.4985

### 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

### Location

Administration, Design,  
Manufacturing, Distribution

Crosstex International  
6789 W. Henrietta Road  
Rush, NY 14543  
USA  
File No.: CM19.4985

Manufacturing

Crosstex International  
31 Water Street  
Cuba, NY 14727  
USA  
File No.: CM19.4985/A

Distribution

Crosstex International  
1600 Marketplace Drive  
Henrietta, NY 14623  
USA  
File No.: CM19.4985/B

Manufacturing

Crosstex International  
534 Vine Street  
Sharon, PA 16146  
USA  
File No.: CM19.4985/C

**Verified by:  
Operations Manager**