

NSAI

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

The National Standards Authority of Ireland certifies that:

SPSmedical Supply Corp
a subsidiary of Crosstex International Inc.
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.

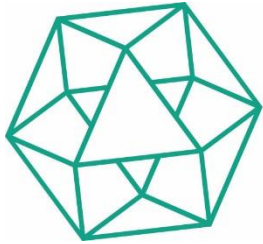
Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4985)

Approved by:
Geraldine Larkin
Chief Executive Officer

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

Registration Number: MD19.4985
Certification Granted: June 29, 2016
Effective Date: April 27, 2021
Expiry Date: April 06, 2023





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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

SPSmedical Supply Corp
a subsidiary of Crosstex International Inc.
6789 W. Henrietta Road
Rush, NY 14543
USA
File No.: MD19.4985

Manufacturing

SPSmedical Supply Corp
a subsidiary of Crosstex International Inc.
31 Water Street
Cuba, NY 14727
USA
File No.: MD19.4985/A

Distribution

SPSmedical Supply Corp
a subsidiary of Crosstex International Inc.
1600 Marketplace Drive
Henrietta, NY 14623
USA
File No.: MD19.4985/B

Manufacturing

SPSmedical Supply Corp
a subsidiary of Crosstex International Inc.
534 Vine Street
Sharon, PA 16146
USA
File No.: MD19.4985/C

**Verified by:
Operations Manager**