

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Andersen Sterilizers, Inc.

(FIN F003463)

Main Site: 3154 Caroline Drive, Health Science Park

Haw River, North Carolina, 27258, USA

Additional sites: Refer to appendix

has been registered by Intertek, an MDSAP recognized auditing organization,
as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

The design, manufacture, service and installation of ethylene oxide gas sterilizers. The design and manufacture of sterilization accessories (biological indicators, exposure indicators, dosimeters), sterilization bags, appropriate ampules, cartridges, abators for the medical device industry.

(An appendix is also part of this certificate of registration)

Certificate Number:

0085440-03

Initial Certification Date:

2018-12-21

Date of Certification Decision:

2024-12-07

Certification Effective Date:

2024-12-20

Certification Expiry Date:

2027-12-20



intertek

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President, Business Assurance

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APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

Andersen Sterilizers, Inc.

This appendix is linked to the Main Certificate # 0085440-03 and cannot be shown nor reproduced without it.

Main Site: 3154 Caroline Drive, Health Science Park, Haw River, North Carolina, 27258, United States (FIN F003463)

Scope: Manufacture of sterilizers and abators.

Additional Site 1: 3170 Caroline Drive, Health Science Park, Haw River, North Carolina, 27258, United States

Scope: Design & Development, purchasing, quality and regulatory activities, manufacture of sterilizer cabinets and injection molded assemblies for cartridges, sterilizer cabinets and dosimeters

Additional Site 2: 3181 Caroline Drive, Health Science Park, Haw River, North Carolina, 27258, United States

Scope: Manufacture of EO sterilization kits, filling of EO ampoules.

Additional Site 3: 3202 Caroline Drive, Health Science Park, Haw River, North Carolina, 27258, United States

Scope: Manufacture of accessories to include dosimeters, exposure indicators, distribution, sales, installation, field service, IT, customer service, HR, and facilities maintenance.

Additional Site 4: 3151 Caroline Drive, Health Science Park, Haw River, North Carolina, 27258, United States

Scope: Office Space - CEO and Engineers.

