

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

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

ISO 13485:2016

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

Certificate Number:

0085440-01

Initial Certification Date:

2018-12-21

Date of Certification Decision:

2022-01-13

Certification Effective Date:

2022-01-13

Certification Expiry Date:

2024-12-20



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