

# 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



**intertek**

**Calin Moldoveanu**

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