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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

PRIMUS Sterilizer Company LLC

Main Site: 175 North US Highway 281
Great Bend, Kansas 67530 United States (F002946)

Additional site: 110 Tech Dr
Sanford, Florida, 32771, United States (F002945)

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, development, manufacture, installation and service of steam sterilizers for healthcare including laboratory applications.

Main site (KS): Manufacturing and purchasing

Additional site (FL): Management, design, manufacturing

Certificate Number:
0107658

Revision Level: 05

Initial Certification Date:
2020-11-20

Certification Effective Date:
2025-09-21

Certification Expiry Date:
2028-09-21

ISO 13485:2016 CERTIFICATION TM
intertek

MDSAP
Medical Device Single Audit Program

Rathin Grover
President, Business Assurance

Intertek Testing Services NA, Inc.
4700 Broadmoor SE, Suite 200
Kentwood, MI, USA, 49512

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request. Validity of this certificate may be verified at http://www.intertek.com/business-assurance/certificate-validation/