



America

CERTIFICATE

No. QS6 105653 0002 Rev. 06

Certificate Holder: **Advanced Sterilization Products, Inc.**
33 Technology Drive
Irvine CA 92618-9824
USA

Certification Mark:



Scope of Certificate: **Design and Development, Production, Servicing, Installation and Distribution of Sterilization / Disinfection Systems and Accessories (Cassettes, Kits, Sterilization Packaging, Instruments Trays and Mats, Chemical Indicator and Test Strips, Biological Indicator, Biological Incubator, and Readers, Test Packs, Boosters and Adaptors, Medical Instruments Detergents)**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_105653_0002_Rev.06

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001166**
Report No.: **72191702**
Effective Date: **2023-12-01**
Expiry Date: **2026-11-30**

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Date of Issue: 2023-11-16

(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
 - RDC ANVISA n. 551/2021
 - RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
 - Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

Facility(ies):

Advanced Sterilization Products, Inc.

33 Technology Drive, Irvine CA 92618-9824, USA

Advanced Sterilization Products, Inc.

31 Technology Drive, Irvine CA 92618-9824, USA

Advanced Sterilization Products, Inc.

11811 Landon Drive, Ste. 300, Mira Loma CA 91752, USA

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Facility Scopes:

Advanced Sterilization Products, Inc.

33 Technology Drive, Irvine CA 92618-9824, USA

Research and Development, Quality, Manufacturing, Servicing, Installation of Sterilization / Disinfection Systems and Accessories (Cassettes, Kits, Sterilization Packaging, Instrument Trays and Mats, Chemical Indicators and Test Strips, Biological Indicators and Readers, Test Packs, Boosters and Adaptor, Biological Incubator and Readers and Medical Instruments Detergents)

REPs Facility ID: F001166

Advanced Sterilization Products, Inc.

31 Technology Drive, Irvine CA 92618-9824 , USA

Biological Indicators Manufacturing, Test Packs Manufacturing, Document Control, Supply Chain and Quality

REPs Facility ID: F001166

Advanced Sterilization Products, Inc.

11811 Landon Drive, Ste 300, Mira Loma, CA 91752, USA

Incoming Inspection, Shipping, Distribution, Warehouse Storage

REPs Facility ID: F001166

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