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## Apostille

(Convention de La Haye du 5 octobre 1961)

1. District of Columbia, United States of America
2. This public document has been signed by BEHZAD SAMYA
3. acting in the capacity of NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA  
BEHZAD SAMYA, NOTARY PUBLIC IN AND FOR THE
4. bears the seal/stamp of DISTRICT OF COLUMBIA
5. at Washington, D.C.
6. the 4 day of DECEMBER 2023
7. by Secretary of the District of Columbia
8. No. 700072
9. Seal
10. Signature:



*Kimberly A. Bassett*

Kimberly A. Bassett  
Secretary of the District of Columbia

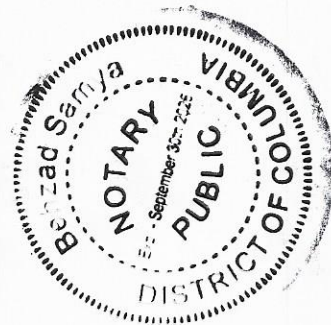


**EU DECLARATION OF CONFORMITY  
(MDR 2017/745)**

Document No.:  
**DoC-MDR- M-13826**  
Revision: C

Legal Manufacturer (Name and Address):	Advanced Sterilization Products, Inc. 33 Technology Drive Irvine, California 92618 USA
European Authorized Representative:	ASP, The Netherlands BV BIC 1, 5657 BX, Eindhoven, The Netherlands
Product Name:	APTIMAX™ Instrument Trays
Basic UDI-DI:	70105A070000000000000007FR
Product Code(s)/Product Family Code and Description:	Refer to Attachment 1 for product codes and description.
Intended Use/Purpose:	The APTIMAX Instrument Trays are designed to encase surgical instruments for sterilization in STERRAD™ Sterilization Systems: STERRAD 100S, STERRAD NX™ (with or without ALLClear™ Technology), STERRAD 100NX (with or without ALLClear Technology).
Classification:	Class I (Annex VIII, Rule 1)
EMDN Code:	S010401
GMDN Code:	12143
Technical Documentation (TD) Number:	TD-M-13826
Single Registration Number (SRN):	US-MF-000008427
Start of CE-Marking:	November 14, 2002
Physical Manufacturer:	Hi-Tech Mold & Tool, Inc. 1 Technology Drive West Pittsfield, MA 01201 USA

State of District of Columbia  
I certify this to be a complete, exact and true copy of the original document.  
certified this 4<sup>th</sup> day of December, 2023.  
Behzad Samya  
BEHZAD SAMYA, Notary Public  
My Commission Expires September 30, 2026



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We, Advanced Sterilization Products, Inc., hereby declare that we are solely responsible for the above listed Medical Device(s), and the Medical Device(s) complies with Medical Device Regulation (EU) 2017/745.  
This EU Declaration of Conformity remains valid until a modification is necessitated by a conformity related change or the expiration of the EN ISO 13485 Certificate.

*Marcelo Trevino**November 1 2023*

Irvine, California, USA

Marcelo Trevino/ Vice President, Global  
Regulatory Affairs

Date of Issue

Place of Issue



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## ATTACHMENT 1

<b>Legal Manufacturer's Name:</b>	Advanced Sterilization Products, Inc.
<b>Product Name:</b>	APTIMAX Instrument Trays
<b>TD Number:</b>	TD-M-13826

List of Product Codes	
Product Code	Product Description
13826	APTIMAX Instrument Trays, 300 mm x 100 mm x 50 mm
13827	APTIMAX Instrument Trays, 450 mm x 100 mm x 50 mm
13828	APTIMAX Instrument Trays, 600 mm x 100 mm x 50 mm
13829	APTIMAX Instrument Trays, 300 mm x 200 mm x 50 mm
13830	APTIMAX Instrument Trays, 450 mm x 200 mm x 50 mm
13831	APTIMAX Instrument Trays, 600 mm x 200 mm x 50 mm
13832	APTIMAX Instrument Trays, 180 mm x 75 mm x 30 mm
13833	APTIMAX Instrument Trays, 250 mm x 150 mm x 30 mm
13834	APTIMAX Instrument Trays, 380 mm x 150 mm x 30 mm
13835	APTIMAX Instrument Trays, 380 mm x 250 mm x 30 mm
13836	APTIMAX Instrument Trays, 278 mm x 270 mm x 100 mm
13837	APTIMAX Instrument Trays, 570 mm x 270 mm x 100 mm
13838	APTIMAX Instrument Trays, 596 mm x 321 mm x 100 mm