EU DECLARATION OF CONFORMITY (MDR 2017/745)

Document No.:
DoC-MDR-M-82010
Revision: **A**

Digitally signed by CÔNG TY TNHH SẢN PHẨM KHỬ TRÙNG CAO CẤP VIỆT NAM
Date: 2022-06-02 17:59+07:00

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:	CIDEX™ Instrument Tray Systems
Basic UDI-DI:	70105A110000000000000117D
Product Code(s)/Product Family Code and Description:	Refer to Attachment 1 for product codes and description.
Intended Use/Purpose:	The CIDEX Instrument Tray Systems are used to contain cleaning and disinfecting fluid for the pre-cleaning and disinfecting of reusable medical instruments.
Classification:	Class I (Annex VIII, Rule 1)
GMDN Code:	12143
Technical Documentation (TD) Number:	TD-M-82010
Single Registration Number (SRN):	US-MF-000008427
Start of CE-Marking:	May 25, 2005
Physical Manufacturer:	Hi-Tech Mold & Tool, Inc. 1 Technology Drive West Pittsfield, MA 01201 USA

We, Advanced Sterilization Products, Inc., hereby declare that we are solely responsible for the above listed devices, and the devices comply 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.

01/19/22

Irvine, California, USA

Carolyn Shelton / Vice President, Global Regulatory & Medical Affairs	Date of Issue	Place of Issue

EU DECLARATION OF CONFORMITY (MDR 2017/745)

ATTACHMENT 1

Legal Manufacturer's Name:	Advanced Sterilization Products, Inc.
Product Name:	CIDEX Instrument Tray Systems
TD Number:	TD-M-82010

List of Product Codes		
Product Code	**Product Description**	
82010	CIDEX Instrument Tray Systems	177 mm x 344 mm x 132 mm
82016		186 mm x 503 mm x 132 mm
82027		220 mm x 740 mm x 136 mm
82032		489 mm Top OD x 718 mm x 222 mm
82076		381 mm x 594 mm x 141 mm