

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

Document No.:
DoC-MDR-M-2258
Revision: **B**

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: CIDEZYME™ Enzymatic Detergent

Basic UDI-DI: 70105A1000000000000000105N

Product Code(s)/Product Family Code and Description: 2258 / CIDEZYME Enzymatic Detergent, 1 Liter Bottle
2260 / CIDEZYME Enzymatic Detergent, 5 Liter Bottle

Intended Use/Purpose: The CIDEZYME Enzymatic Detergent is intended to be used for pre-soaking and pre-cleaning instruments prior to disinfection or sterilization in accordance with instrument manufacturers' recommendations.

Classification: Class I (Annex VIII, Rule 1)

GMDN Code: 63385

Technical Documentation (TD) Number: TD-M-2258

Start of CE-Marking: February 4, 1999

Physical Manufacturer: Weiman Products, LLC
755 Tri-State Parkway
Gurnee, Illinois 60031
USA

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



11 March 2021

Irvine, California, USA

Carolyn Shelton / Vice President, Global
Regulatory & Medical Affairs, Product Stewardship

Date of Issue

Place of Issue