



DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Manufacturer: ADVANCED STERILIZATION PRODUCTS
Division of Ethicon, Inc.
A Johnson & Johnson Company
33 Technology Drive
Irvine, California 92618

European Authorized Representative: Johnson & Johnson Medical GmbH
Robert-Koch-Straße 1, 22581 Norderstedt,
Germany

Product: CIDEZYME Enzymatic Detergent

Product Code(s)/Product Family Code and Description: 2258, 2260
CIDEZYME Enzymatic Detergent is used for pre-soaking and pre-cleaning instruments prior to disinfection or sterilization in accordance with instrument manufacturers' recommendations.

Classification: Class I (Annex IX, Rule 1)

GMDN Code: 63385

MDD TF Number: TF-M-2258

Start of CE-Marking: February 4, 1999

RoHS TF Number (If applicable): N/A

We, Advanced Sterilization Products Division of Ethicon, Inc., hereby declare that we are solely responsible for the above listed Medical Device(s), and the Medical Device(s) complies with Council Directive 93/42/EEC as amended by 2007/47/EC.

This Declaration of Conformity remains valid until a modification is necessitated by a conformity related change. The applied harmonized standards are listed with the Essential Requirements Checklist which resides in the Technical Files.



Elsie Kim

31 March 2020

Irvine, California

Elsie Kim/Manager, Regulatory
Affairs/ASP

Date of Issue

Place of Issue

Revision History

Revision	Summary of Changes	Release Date
A	Initial Release	01/31/2019
B	Updated due to revision of Technical File to reflect new ISO 13485 certificate numbers for legal and physical manufacturers.	03/31/2020