



## Regulatory Affairs

No. TF-2258-002

### DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

(according to Annex II excl. Section 4 of Council Directive 93/42/EEC)

We, **ADVANCED STERILIZATION PRODUCTS**

Division of Ethicon, Inc.  
A Johnson & Johnson Company  
33 Technology Drive  
Irvine, California 92618

Hereby declare that we are solely responsible for the medical device

Product Name: **CIDEZYME® Enzymatic Detergent**  
Product Code: **2258, 2260**

European Representative: **Johnson & Johnson Medical GmbH**  
**Robert-Koch-Straße 1, 22851 Norderstedt**  
**Germany**

Complies with the essential requirements of the Council Directive 93/42/EEC  
(Medical Device Directive, MDD) of June 14, 1993.

Classification (MDD Annex IX, Rule 1): **Class I**

This Declaration of Conformity refers to the above product marketed since October  
17, 2013.

It remains valid until a valid modification is necessitated by a conformity related  
change, whereupon a new conformity declaration will be issued.

The conformity was proven by a conformity assessment procedure according to  
Annex VII of the Directive mentioned above.

The applied harmonized standards are listed with the Essential Requirements  
Checklist which resides in the Technical File.

Amy Smith  
Worldwide Director, Regulatory Affairs

February 24, 2015  
Date

**ADVANCED STERILIZATION PRODUCTS®**

Division of Ethicon, Inc.

a **Johnson & Johnson** company