

STERIS



## EC Declaration of Conformity

Manufacturer: STERIS Corporation  
7501 Page Avenue  
St. Louis, MO  
63133

EC Authorized Representative: STERIS Limited  
Chancery House, 190 Waterside Road  
Hamilton Industrial Park, Leicester  
LE5, 1QZ, UK

Classification: Class I, according to MDD, Annex IX, Rule 1

Product Name: PRE-Klenz™ Neutral pH Detergent

Product Code: 1503

---

We herewith declare that the above mentioned product(s) meet the provisions of Council Directive 93/42/EEC as amended by 2007/47/EC for Medical Devices. The product has been subjected to conformity assessment procedure according to Article 11, paragraph 5 of the Medical Device Directive 93/42/EEC (Annex VII). All supporting documentation is retained on the premises of the manufacturer.


**Standards applied:** ISO 13485

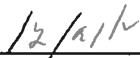
**Quality System Certificate(s)** FM 40430

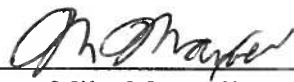
**Start of CE-marking:** April 14, 2008

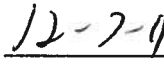
**Place, Date of issue:** STERIS Corporation, St. Louis, MO USA

On behalf of STERIS Corporation,

  
\_\_\_\_\_  
Name Mike Ebers  
Title Director, Regulatory Affairs

  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Name Mike Maxwell  
Title Manager, Quality Systems and Quality Control

  
\_\_\_\_\_  
Date