

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

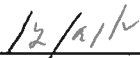
Start of CE-marking: April 14, 2008

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

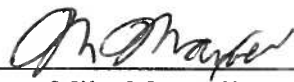
On behalf of STERIS Corporation,



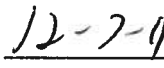
Name Mike Ebers
Title Director, Regulatory Affairs



Date 12/2/12



Name Mike Maxwell
Title Manager, Quality Systems and Quality Control



Date 12-2-12