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 — Date 12/21/12
Title Director, Regulatory Affairs

Name Mike Maxwell — Date 12-7-9
Title Manager, Quality Systems and Quality Control