



EC Declaration of Conformity

Manufacturer: **Sterisets Medical Products**
Zona Industrial 1 – Lote 11 a 14
4560-164 Guilhufe – Penafiel
Portugal
Tel: +351 255 729 090
website: www.sterisets.com
E-mail: info@sterisets.eu

Product category: Sterile catheterization accessory sets, sterile single use forceps, clamps and scissors, sterile and non sterile dressing sets, sterile dialysis sets, sterile delivery sets, sterile surgical sets, sterile washing sets, sterile and non sterile gauze and non woven swabs and balls and sterile syringes with 0,9% sodium chloride

Classification: According to Annex IX of Council Directive 93/42/EEC of 14th June 1993
Class IIa

Conformity assessment route: Annex II


CE certificate no.: 2153004CE02

ISO 13485 certificate no.: 2153004

Notified Body: DEKRA Certification B.V.

CE marking: CE0344

We hereby declare that the above mentioned medical devices meet the provisions of the Council Directive 93/42/EEC of 14th June 1993 including all subsequent amendments, of the Portuguese Law by Decreto-Lei nº 145/2009 of 17th June, and of the Dutch MDD2007 Besluit Medische Hulpmiddelen.

Signature: 

Name: Jos van der Kwartel

Position: CEO

Date: 01-07-2016