



## *EC Declaration of Conformity*

**Manufacturer:** Steripack SA  
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Portugal  
Tel: +351 255 729 090  
Email [info@sterisets.eu](mailto:info@sterisets.eu)  
[www.sterisets.com](http://www.sterisets.com)

**Product category:** Sterile examination gloves, sterile absorbent pads, sterile trays and bowls, sterile syringes with water, sterile syringes with water containing 10% glycerin, sterile surgical drapes, sterile catheterization accessory sets, sterile washing sets, sterile dressing sets and sterile suture accessory sets

**Classification:** According to Annex IX of Council Directive 93/42/EEC of 14<sup>th</sup> June 1993  
Class I sterile

**Conformity assessment route:** Annex II

**CE certificate no.:** 2153004CE01

**ISO 13485 certificate no.:** 2153004

**Notified Body:** DEKRA Certification B.V.

**CE marking:** CE0344

**CE mark was first applied on:** 08-09-2012

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

**Signature:**   
**Name:** Isabel Nascimento  
**Position:** Management representative  
**Date:** 28-03-2019