

EC CERTIFICATE

Number: 2153004CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

Sterisets Medical Products

Zona Industrial 1 - Lote 11 a 14

4560-164 Guilhufo

Penafiel

Portugal

For the product category(ies)

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

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

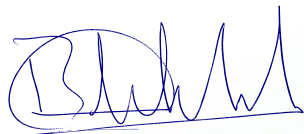
Certification Notice 2153004CN, initially dated 8 September 2012
Addendum, initially dated 8 September 2012

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex II Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 September 2023
Issued for the first time: 8 September 2012
Revised: 15 April 2016
Reissued: 2 November 2018

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2153004CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

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

Issued to:

Sterisets Medical Products

**Zona Industrial 1 - Lote 11 a 14
4560-164 Guilhufe
Penafiel
Portugal**

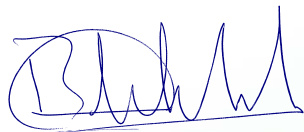
This certificate covers the following product(s):

- Sterile examination gloves
- Sterile absorbent pads
- Sterile trays and bowls
- Sterile syringes with water
- Sterile syringes with water containing 10% glycerine
- Sterile surgical drapes
- Sterile catheterization accessory sets
- Sterile washing sets
- Sterile dressing sets
 - o Sterile spatulas
 - o Sterile maternity pads
 - o Sterile cotton tips
- Sterile suture accessory sets

Initial date: 8 September 2012

Revision date: 1 September 2015

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B.T.M. Holtus
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