

EC CERTIFICATE

Number: 2153004CE02

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V
(Devices in Class IIa, IIb or III)

Manufacturer:

Sterisets Medical Products

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

For the product category(ies)

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

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 for the manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex V of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory.

The necessary information related to the quality assurance 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 2018
Issued for the first time: 8 September 2012
Reissued: 1 September 2015

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2153004CE02

1/2

CE MARKING OF CONFORMITY MEDICAL DEVICES

Sterile catheterization accessory sets, 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

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 catheterization accessory sets
- Sterile and non sterile dressing sets
- Sterile dialysis sets
- Sterile delivery sets
- Sterile surgical sets
 - o Sterile anaesthesia sets
 - o Sterile puncture sets
 - o Sterile suture accessory sets
- Sterile washing sets

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ADDENDUM

Belonging to certificate: 2153004CE02

2/2

CE MARKING OF CONFORMITY MEDICAL DEVICES

Sterile catheterization accessory sets, 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

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- Sterile and non sterile gauze and non woven swabs and balls
 - o Sterile and non sterile gauze balls
 - o Sterile and non sterile gauze balls on a pin
 - o Sterile and non sterile gauze balls star shape
 - o Sterile and non sterile gauze balls tampon
 - o Sterile and non sterile gauze balls triangular shape
 - o Sterile and non sterile gauze balls with X-ray
 - o Sterile and non sterile gauze swabs with X-ray
 - o Sterile and non sterile abdominal swabs with X-ray
 - o Gauze swabs flat
 - o Preparation balls with X-ray
 - o Sterile and non sterile non woven balls
 - o Sterile and non sterile non woven balls triangular shape
 - o Non woven balls on a pin
 - o Non woven balls with X-ray
 - o Non woven swabs with X-ray
 - o Sterile syringes with 0,9% sodium chloride.
- Sterile forceps, clamps and scissors

Initial date: 8 September 2012

Revision date: 1 September 2015

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