EC CERTIFICATE

Number: 2153004CE04

Full Quality Assurance System

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

Single use surgical, dental and podiatry instruments

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 2 July 2015

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 design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. 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: 25 October 2022
Issued for the first time: 2 July 2015
Reissued: 17 April 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2153004CE04

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Single use surgical, dental and podiatry instruments

Issued to:

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

This certificate covers the following product(s):

- Single use Forceps
- Single use Needle Holders
- Single use Scissors
- Single use Retractors
- Single use Suction tubes
- Single use Trocars
- Single use Uterine cannula
- Single use Uterine curettes
- Single use Uterine dilators
- Single use IUCD hooks
- Single use Vaginal specula
- Single use Uterine Sounds
- Single use Curettes
- Single use Dilators
- Single use Hooks
- Single use Probes

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Belonging to certificate: 2153004CE04

CE MARKING OF CONFORMITY
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Single use surgical, dental and podiatry instruments

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- Single use Bone cutters
- Single use Elevators
- Single use Bone leavers
- Single use Perforators
- Single use Chisel with hook curette
- Single use Chisels
- Single use Dissectors
- Single use Skin hooks
- Single use Raspetories
- Single use Dental Syringes
- Single use Wire saw sets
- Single use Dissectors/specula
- Single use Dental probes
- Single use Rongeur
- Single use Artery Clips

Initial date: 2 July 2015
Revision date: 20 April 2018
DEKRA Certification B.V.

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