

EC CERTIFICATE

Number: 2081762CE04

Full Quality Assurance System

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

(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

The Surgical Company International B.V.

Beeldschermweg 6F
3821 AH Amersfoort
The Netherlands

For the product category(ies)

Forced Air Heating Equipment intended for Hyperthermia / Hypothermia and sterile heating blankets

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 2081762CN, initially dated 25 April 2005 Addendum, initially dated 9 February 2010

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, 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. 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: 1 March 2023
Issued for the first time: 27 May 2009
Reissued: 1 March 2018

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

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ADDENDUM

Belonging to certificate: 2081762CE04

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Forced Air Heating Equipment intended for Hyperthermia / Hypothermia and sterile heating blankets

Issued to:

The Surgical Company International B.V.

**Beeldschermweg 6F
3821 AH Amersfoort
The Netherlands**

This certificate covers the following product(s):

- Heating equipment: Mistral Air Plus (Class IIb)
- Heating equipment: Mistral-Air (Class IIb)
- Sterile heating blankets: Mistral-Air Sterile Surgical Access Blankets (Class I sterile)

Initial date: 9 February 2010

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan.

ing. A.A.M. Laan
Certification Manager

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