EC CERTIFICATE

Number: 2081762CE03

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

The Surgical Company International B.V.

Beeldschermweg 6F
3821 AH Amersfoort
The Netherlands

For the product category(ies)

Systems for Extra Corporeal Warming of blood, intravenous fluid or irrigation fluid

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 25 July 2006

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: 1 March 2023
Issued for the first time: 16 December 2005
Reissued: 1 March 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
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ADDENDUM

Belonging to certificate: 2081762CE03

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Systems for Extra Corporeal Warming of blood, intravenous fluid or irrigation fluid

Issued to:

The Surgical Company International B.V.
Beeldschermweg 6F
3821 AH Amersfoort
The Netherlands

This certificate covers the following product(s):

- Fluido® Blood and Fluid Warmer (Class IIb)
- Fluido® Irrigation Fluid Warmer (Class IIb)
- Fluido® Air Guard (Class IIb)
- Fluido® Pressure Chamber (Class IIa)
- Fluido® sterile Intravenous disposables (Class IIa)
- Fluido® sterile Irrigation disposables (Class IIa)
- Fluido® Compact Warming Device (Class IIb)
- Fluido® Compact disposables (Class IIa)

Initial date: 25 July 2006

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

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