EC CERTIFICATE

Number: 2153004CE05

Production Quality Assurance

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

Manufacturer:

Steripack S.A.
Zona Industrial 1 - Lote 11 a 14
4560-164 Guilhufe
Penafiel
Portugal

For the product category(ies)

Forced Air Heating Equipment intended for prevention and treatment of Hypothermia

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 18 July 2017

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: 26 May 2024
Issued for the first time: 18 July 2017
Reissued: 6 January 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
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: 2153004CE05

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Forced Air Heating Equipment intended for prevention and treatment of Hypothermia

Issued to:

Steripack S.A.
Zona Industrial 1 - Lote 11 a 14
4560-164 Guilhufe
Penafiel
Portugal

This certificate covers the following product(s):

- Blanket Warming Unit

Initial date: 18 July 2017
Revision date: 4 June 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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