

EC CERTIFICATE

Number:3811335CE01

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:

A & E Medical Corp

5206 Asbury Road

Farmingdale NJ 07727

United States Of America

For the product category(ies)

Temporary cardiac pacing wires, connecting cables, stainless steel sutures and surgical punches

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 3811335CN, initially dated 8 April 2014
Addendum, initially dated 8 April 2014

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: 8 June 2023
Issued for the first time: 8 April 2014
Reissued: 8 June 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

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: 3811335CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Temporary cardiac pacing wires, connecting cables, stainless steel sutures and surgical punches

Issued to:

A & E Medical Corp
5206 Asbury Road
Farmingdale NJ 07727
United States Of America

This certificate covers the following product(s):

Surgical Punches (Class IIa)
Stainless Steel Sutures (Class IIb)
Temporary Cardiac Pacing Wires (Class III)
MYO/Lead Disposable Patient Cable (Class Is)

Initial date: April 8, 2014

Revision date: January 19, 2015

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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