

EC DESIGN-EXAMINATION CERTIFICATE

Number: 3811335DE01

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

Manufacturer:

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

For the product

Temporary Cardiac Pacing Wires

Documents, that form the basis of this certificate:

Certification Notice 3811335CN, initially dated April 8, 2014
CE Marking of Conformity 3811335CE01
Addendum, initially dated 8 April 2014

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, 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, based on an examination in accordance with Annex II (4) of this Directive.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: June 5, 2018
Issued for the first time: April 8, 2014
Reissued: May 5, 2015

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

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: 3811335DE01

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

Temporary Cardiac Pacing Wires

Issued to:

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

This certificate covers the following product(s):

Catalogue #	Style	Description
020-000 to 020-018	Bare End	M20, no curve, standard and extended length, standard and small straight needle; white, orange, Lt. orange
021-000 to 021-018	Small Loop	M21, no curve, standard and extended length, standard and small straight needle; white, orange, Lt. orange
022-000 to 022-018	Large Loop	M22, no curve, standard and extended length, standard and small straight needle; white, orange, Lt. orange
024-100 to 024-418	No Bare End	M24, 1/2 curve needle (standard and small), 3/8 curve needle, reverse cutting curve needle, standard and extended length, standard and small straight needle; white, orange, Lt. orange
025-100 to 025-418	Wing	M25, 1/2 curve needle (standard and small), 3/8 curve needle, reverse cutting curve needle, standard and extended length, standard and small straight needle; white, orange, Lt. orange
026-100 to 026-418	Interrupted	M26, 1/2 curve needle (standard and small), 3/8 curve needle, reverse cutting curve needle, standard and extended length, standard and small straight needle; white, orange, Lt. orange

Initial date: April 8, 2014

DEKRA Certification B.V.



drs. G.J. Zoetbrood
 Managing Director



ing. A.A.M. Laan
 Certification Manager

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