

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:

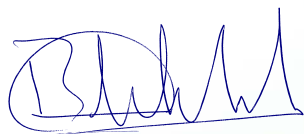
Certification Notice 3811335CN, initially dated April 8, 2014
CE Marking of Conformity 3811335CE01
Addendum, initially dated 8 April 2014

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: 1 November 2022
Issued for the first time: 8 April 2014
Reissued: 8 June 2018

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping letters.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing initial 'J' followed by the name.

J.A. van Vugt
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
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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

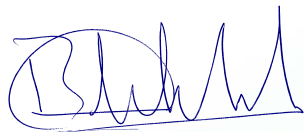
This certificate covers the following product(s):

MONOPOLAR WIRE – EPICARDIAL (Class III)
BIOPOLAR WIRE – EPICARDIAL (Class III)
QUADPOLAR WIRE – EPICARDIAL (Class III)
MONOPOLAR WIRE – MYOCARDIAL – ADULT (Class III)
BIOPOLAR WIRE – MYOCARDIAL – ADULT (Class III)
QUADPOLAR WIRE – MYOCARDIAL – ADULT (Class III)
MONOPOLAR WIRE – MYOCARDIAL – PEDIATRIC (Class III)
BIOPOLAR WIRE – MYOCARDIAL – PEDIATRIC (Class III)
QUADPOLAR WIRE – MYOCARDIAL – PEDIATRIC (Class III)
PACKS (PACING WIRE + FASTLOCK) (Class III)

Initial date: April 8, 2014

Revised date: January 23, 2019

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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