

# CERTIFICATE

Number: 3826271

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## A & E Medical Corp

5206 Asbury Road  
Farmingdale, NJ 07727  
United States Of America

Manufacturer Facility Identifier F004889

Conforms with the following standard and regulatory requirements:

## ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Canada: Medical Devices Regulations - Part 1- SOR 98/282

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act

United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:

Design, manufacture, and distribution of temporary cardiac pacing wires and pacing wire patient cable, metal sutures and associated instruments, cable, plates and cable/plate systems for sternum closure and anterior chest wall stabilization / fixation, suction coagulators, scalp clips, surgical punches, and connecting cables to transmit electrical signals for surgical instrumentation for use in cardiothoracic and surgical interventions.

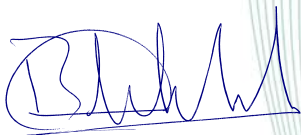
Certificate expiry date: 20 December 2023

Certificate effective date: 21 December 2020

Certified since: 21 December 2020

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:  
<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.





# ADDENDUM

To certificate: 3826271

The management system of the organization(s) and/or location(s) of:

## A & E Medical Corp

5206 Asbury Road  
Farmingdale, NJ 07727  
United States Of America

Certified organization(s) and/or locations:

A & E Medical Corp.  
1340 Campus Parkway, Unit 3B  
Wall Township, NJ 07753

Finished goods warehousing and shipping

Addendum expiry date: 20 December 2023  
Addendum effective date: 21 December 2020