

CERTIFICATE

Number: 2194636

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

Assut Medical Sàrl

Avenue de Rochettaz 57

1009 Pully

Switzerland

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

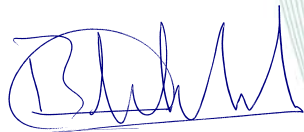
Scope:

Design, manufacturing and distribution of sterile surgical sutures, pacing wires, micro-surgical knives and non-sterile atraumatic needles for the area of surgery

Certificate expiry date: 22 February 2023
Certificate effective date: 22 February 2020
Certified since: 20 September 2016

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



ADDENDUM

To certificate: 2194636

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

Assut Medical Sàrl

Avenue de Rochettaz 57
1009 Pully
Switzerland

Certified additional organization(s) and/or locations:

Organization/Location

Assut Medical Sàrl

Sur le Crêt 13
2606 Corgemont
Switzerland

Scope:

Design and manufacturing of sterile surgical sutures, pacing wires, micro-surgical knives and non-sterile atraumatic needles for the area of surgery

Assut Medical Sàrl

Av. De Lavaux 35 P.O. Box 5
CH-1009 Pully / Lausanne
Switzerland

Scope:

Design and distribution of sterile surgical sutures, pacing wires, micro-surgical knives and non-sterile atraumatic needles for the area of surgery

Addendum expiry date: 22 February 2023

Addendum effective date: 22 February 2020

EC CERTIFICATE

Number: 2194636CE02

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III)

Manufacturer:

Assut Medical Sàrl

Av. de Rochettaz 57

1009 Pully

Switzerland

For the product category(ies)

Temporary Pacing Wire

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 2194636CN, initially dated 20 September 2016

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 for the above mentioned product category in accordance to the provisions of Annex II of 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: 12 December 2022
Issued for the first time: 23 September 2016
Reissued: 12 December 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2194636DE02

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

Manufacturer:

Assut Medical Sàrl
Avenue de Rochettaz 57
1009 Pully
Switzerland

For the product

Temporary Pacing Wire made of multifilament steel

Documents, that form the basis of this certificate:

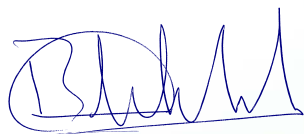
Certification Notice 2194636CN, initially dated 20 September 2016
CE Marking of Conformity 2194636CE02

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 manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

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: 2 October 2023
Issued for the first time: 23 September 2016
Revised: 4 April 2019
Reissued: 1 October 2018

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

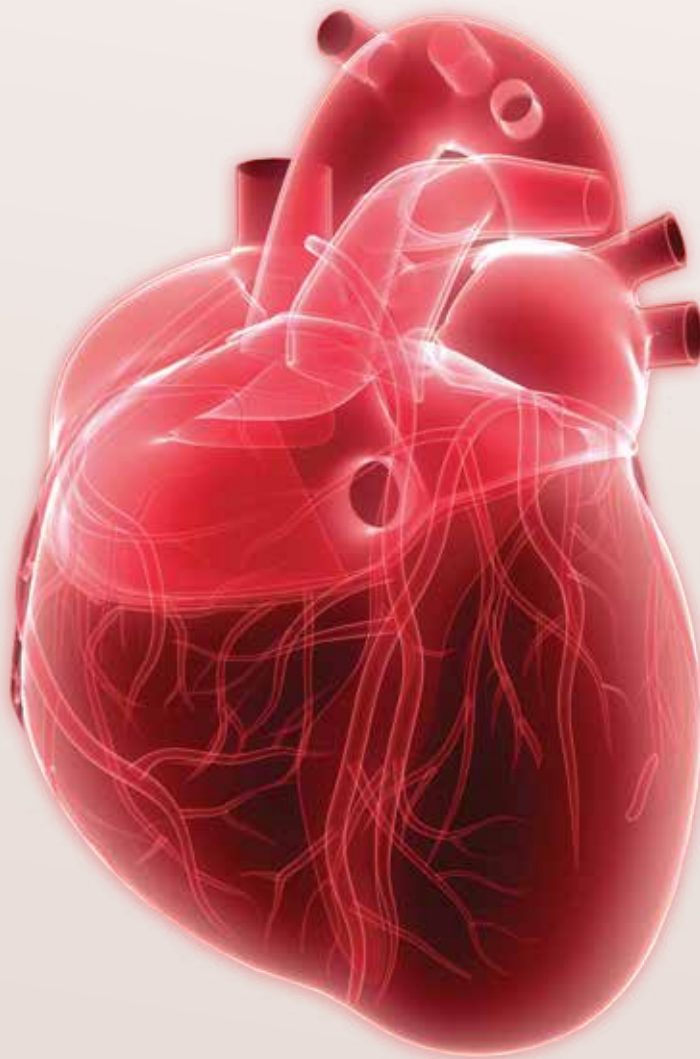
DEKRA Certification B.V. is Notified Body with ID no 0344

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

Assut sutures

of Switzerland

Vascular & Cardiovascular Sutures



A leading Swiss brand, well-known worldwide

Temporary Cardiac Pacing Wire

A very fine braided multifilament stainless steel wire of excellent flexibility with coloured Polyethylen insulation, easy to identify. A special straight cutting needle with breakaway feature, combined with a round - bodied needle or with a cutting taper needle or loop.

Needle code	USP	EP	CM	Colour	Product No. (REF)
HR 17 + RSK 90	3-0	2	60	blue	CVP 660
HR 25 + RSK 90	2-0	3	60	blue	CVP 151
HR 17 + RSK 58	3-0	2	60	blue	CVP 656
	2-0	3	60	blue	CVP 658
HSR 18 + RSK 58	3-0	2	60	blue	CVP 652
HSR 25 + RSK 58	3-0	2	60	blue	CVP 653
HSR 18 + RSK 65	3-0	2	60	blue	CVP 13
HSR 25 + RSK 65	3-0	2	60	blue	CVP 15
HSR 12 + RSK 58	3-0	2	60	blue	CVP 651
LOOP + RSK 90	2-0	3	60	white	CVP 220
	2-0	3	60	blue	CVP 221

Assut sutures

of Switzerland

Assut Medical Sàrl

P.O. Box 5

CH - 1009 Pully-Lausanne

Switzerland

Tel. ++41-21-728.64.35

Fax. ++41-21-728.64.49

Email : info@assutsutures.com

www.assutsutures.com