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 2020
Certificate effective date: 27 February 2019
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

Digitally signed by Captari Vladimir
Date: 2020.01.21 13:19:29 EET
Reason: MoldSign Signature
Location: Moldova

MGMT. SYS. RvA C 589

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:
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 2020
Addendum effective date: 27 February 2019

EC CERTIFICATE

Number: 2194636CE01

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

Avenue de Rochettaz 57
1009 Pully
Switzerland

For the product category(ies)

Non-absorbable surgical sutures

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
Addendum, initially dated 23 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.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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: 2194636CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Non-absorbable surgical sutures

Issued to:

Assut Medical Sàrl
Avenue de Rochettaz 57
1009 Pully
Switzerland

This certificate covers the following product(s):

- Astralen (Polyester) with or without pledgets – Class III
- Nylon (Polyamide) – Class III
- Polypropylene – Class III
- Silk – Class III
- PTFE Pledgets – Class III
- Supramid (Polyamide) – Class IIa
- Surgical Steel – Class IIb
- Astralen/Polyester Tape – Class IIb
- AssuTopFiber® (UHMWPE) – Class IIb, Rule 8

Initial date: 23 September 2016
Revision date: 4 April 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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EC DESIGN-EXAMINATION CERTIFICATE

Number: 2194636DE01

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

Non-absorbable surgical sutures

Documents, that form the basis of this certificate:

Certification Notice 2194636CN, initially dated 20 September 2016
CE Marking of Conformity 2194636CE01
Addendum, initially dated 23 September 2016

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: 22 February 2023
Issued for the first time: 23 September 2016
Reissued: 22 February 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 2194636DE01

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Non-absorbable surgical sutures

Issued to:

Assut Medical Sàrl
Avenue de Rochettaz 57
1009 Pully
Switzerland

This certificate covers the following product(s):

Astralen (Polyester) with or without pledgets

Nylon (Polyamide)

Polypropylene

Silk

PTFE Pledgets

Initial date: 23 September 2016
Revision date: 4 April 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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