

# 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**

**Av. 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: 22 February 2018  
Issued for the first time: 23 September 2016

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
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  
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

# ADDENDUM

Belonging to certificate: 2194636CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Non-absorbable surgical sutures

Issued to:

**Assut Medical Sàrl**  
**Av. de Rochettaz 57**  
**1009 Pully**  
**Switzerland**

This certificate covers the following product(s):

Astralen (Polyester) with or without pledgets – Class III, GMDN 13906

Nylon (Polyamide 6) – Class III, GMDN 38000

Polypropylene – Class III, GMDN 13909

Silk – Class III, GMDN 13910

PTFE Pledgets – Class III, GMDN 31744

Supramid (Polyamide 6.6) – Class IIa, GMDN 38000

Surgical Steel – Class IIb, GMDN 13904

Astralen/Polyester Tape – Class IIb, GMDN 46242

AssuTopFiber (UHMWPE) – Class IIb, Rule 8, GMDN 13907

Initial date: 23 September 2016

Revision date: 19 July 2017

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of ing. A.A.M. Laan.

ing. A.A.M. Laan  
Certification Manager

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