

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:

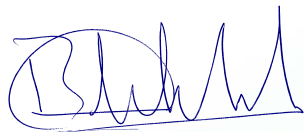
Certification Notice 2194636CN, initially dated 20 September 2016
CE Marking of Conformity 2194636CE01
Addendum, initially dated 23 September 2016

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.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, sweeping initial 'J' followed by a series of connected loops.

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

ADDENDUM

Belonging to certificate: 2194636DE01

1/1

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

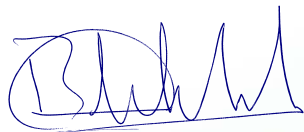
Silk

PTFE Pledgets

Initial date: 23 September 2016

Revision date: 4 April 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of a stylized, cursive script.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, consisting of a stylized, cursive script.

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