

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2194636DE01

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

Manufacturer:

Assut Medical Sàrl
Av. 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 2018
Issued for the first time: 23 September 2016

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan
Certification Manager

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

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ADDENDUM

Belonging to certificate: 2194636DE01

1/1

EC DESIGN-EXAMINATION 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 –GMDN 13906

Nylon (Polyamide 6) – GMDN 38000

Polypropylene – GMDN 13909

Silk – GMDN 13910

PTFE Pledgets – GMDN 31744

Initial date: 23 September 2016

Revision date: 19 July 2017

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, consisting of a stylized 'Z' followed by 'oetbrood'.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, consisting of a stylized 'L' followed by 'aan'.

ing. A.A.M. Laan
Certification Manager

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