

EC CERTIFICATE

Number: 2194636CE03

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)

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.



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
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ADDENDUM

Belonging to certificate: 2194636CE03

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Absorbable surgical sutures

Issued to:

Assut Medical Sàrl
Av. de Rochettaz 57
1009 Pully
Switzerland

This certificate covers the following product(s):

- AssuCryl® MonoSlow (PDO) - GMDN 16584
- AssuCryl® Lactin (PGLA) - GMDN 17471
- AssuCryl® (PGA) - GMDN 13908
- AssuCryl® Rapid (PGA) - GMDN 13908
- AssuCryl® MonoRapid (PGCL) - GMDN 45814

Initial date: 23 September 2016

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, consisting of a stylized, cursive script.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, consisting of a stylized, cursive script.

ing. A.A.M. Laan
Certification Manager

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