

# EC DESIGN-EXAMINATION CERTIFICATE

Number: 2194636DE03

**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

**Absorbable surgical sutures**

Documents, that form the basis of this certificate:

**Certification Notice 2194636CN, initially dated 20 September 2016**  
**CE Marking of Conformity 2194636CE03**  
**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: 12 December 2022  
Issued for the first time: 23 September 2016  
Reissued: 12 December 2017

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

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: 2194636DE03

1/1

## EC DESIGN-EXAMINATION 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 first name and a last name.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of ing. A.A.M. Laan, consisting of a stylized first name and a last name.

ing. A.A.M. Laan  
Certification Manager

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