

# EC DESIGN-EXAMINATION CERTIFICATE

Number: 2162627DE05

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

Manufacturer:

**Institut Straumann AG**  
Peter-Merian-Weg 12  
4002 Basel  
Switzerland

For the product

**Straumann® XenoOss**  
**Straumann® Cerabone**

Documents, that form the basis of this certificate:

**Certification Notice 2162627CNCN, initially dated 10 July 2013**  
**CE Marking of Conformity 2162627CE05**  
**Addendum, initially dated 15 November 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. Additionally, DEKRA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of Commission Regulation 722/2012 of 8 August, 2012 concerning medical devices manufactured utilising tissue of animal origin.

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: 20 January 2020  
Issued for the first time: 15 November 2016  
Reissued: 25 May 2018

DEKRA Certification B.V.

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

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of 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: 2162627DE05

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## EC DESIGN-EXAMINATION MEDICAL DEVICES

Straumann® XenoOss  
Straumann® Cerabone

Issued to:

**Institut Straumann AG**  
Peter-Merian-Weg 12  
4002 Basel  
Switzerland

This certificate covers the following product(s):

- 0.5 – 1.0 mm, 1 × 0.5 cc
- 0.5 – 1.0 mm, 1 × 1.0 cc
- 0.5 – 1.0 mm, 1 × 2.0 cc
- 0.5 – 1.0 mm, 1 × 5.0 cc
- 1.0 – 2.0 mm, 1 × 0.5 cc
- 1.0 – 2.0 mm, 1 × 1.0 cc
- 1.0 – 2.0 mm, 1 × 2.0 cc
- 1.0 – 2.0 mm, 1 × 5.0 cc

Initial date: 15 November 2016  
Revision date: 3 January 2017

DEKRA Certification B.V.

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drs. G.J. Zoetbrood  
Managing Director

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

ing. A.A.M. Laan  
Certification Manager

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