

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2162627DE06

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® GBR Membrane
Straumann® Jason Membrane

Documents, that form the basis of this certificate:

Certification Notice 2162627CN, initially dated 10 July 2013
CE Marking of Conformity 2162627CE06
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: 18 June 2019
Issued for the first time: 15 November 2016
Revised: 25 January 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
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: 2162627DE06

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

Straumann® GBR Membrane
Straumann® Jason Membrane

Issued to:

Institut Straumann AG

Peter-Merian-Weg 12
4002 Basel
Switzerland

This certificate covers the following product(s):

- 15 × 20 mm
- 20 × 30 mm
- 30 × 40 mm

Initial date: 15 November 2016

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
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