EC DESIGN-EXAMINATION CERTIFICATE

Number: 2162627DE12

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 2162627CE02
Addendum, initially dated 20 March 2020

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: 23 October 2023
Issued for the first time: 20 March 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
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: 2162627DE12

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):

Porcine Collagen Dental Regeneration Membrane
- 15 × 20 mm
- 20 × 30 mm
- 30 × 40 mm

Initial date: 20 March 2020

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B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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