

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2162627DE03

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

Bone Substitutes, Resorbable, Osteoconductive Bone Filler

Documents, that form the basis of this certificate:

Certification Notice 2162627CN, initially dated 13 July 2013
CE Marking of Conformity 2162627CE04
Addendum, initially dated 17 March 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.

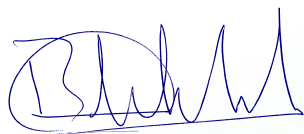
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 December 2023

Issued for the first time: 17 March 2016

Reissued: 6 December 2018

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of a stylized, cursive script.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, consisting of a stylized, cursive script.

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: 2162627DE03

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

Bone Substitutes, Resorbable, Osteoconductive Bone Filler

Issued to:

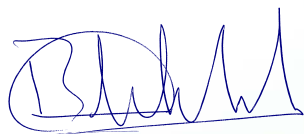
Institut Straumann AG
Peter-Merian-Weg 12
4002 Basel
Switzerland

This certificate covers the following product(s):

- Straumann ®BoneCeramic

Initial date: 17 March 2016
Revision date: 6 December 2018

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B.T.M. Holtus
Managing Director

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