

CERTIFICATE

Number: 2217469

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Institut Straumann AG

Peter-Merian-Weg 12
4002 Basel
Switzerland

Manufacturer DUNS 483599259

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169 and Article 4 to Article 68
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

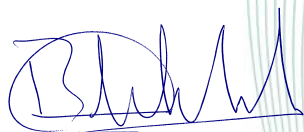
Scope:

Design and Development, Manufacture and Distribution of Regenerative Materials, for dental applications

Certificate expiry date: 2021-12-01
Certificate effective date: 2018-12-06
Certified since: 2018-12-06

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-product-safety.com/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



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ADDENDUM

To certificate: 2217469

The management system of the organization(s) and/or location(s) of:

Institut Straumann AG

Peter-Merian-Weg 12
4002 Basel
Switzerland

Certified organization(s) and/or locations:

Location	Certification scope / Activity
Institut Straumann AG Gartenstrasse 143 4002 Basel Switzerland	Warehouse

Location	Sub certificate nr	Certification scope / Activity
Biora AB Medeon Science Park 205 12 Malmö Sweden	2217469-I	Manufacture and Distribution of Regenerative Materials, for dental applications

Addendum expiry date: 2021-12-01
Addendum effective date: 2018-12-06