straumann

DECLARATION OF CONFORMITY

We, Institut Straumann AG, Peter Merian-Weg 12, CH 4002 Basel, Switzerland declare under our sole responsibility that the following medical device(s)

Art. No.	Article name	Class	Classification Rule	GMDN
010.5100	VITA Mark II Crown by Straumann	II a	8	38594
010.5101	VITA Mark II Partial crown by Straumann	II a	8	38594
010.5102	VITA Mark II Veneer by Straumann	II a	8	38594
010.5103	VITA Mark II Onlay by Straumann	II a	8	38594
010.5104	VITA Mark II Inlay by Straumann	II a	8	38594
010.5150	VITA TriLuxe Crown by Straumann	II a	8	38594
010.5151	VITA TriLuxe Partial crown by Straumann	II a	8	38594
010.5152	VITA TriLuxe Veneer by Straumann	II a	8	38594
010.5153	VITA TriLuxe Onlay by Straumann	II a	8	38594
010.5154	VITA TriLuxe Inlay by Straumann	II a	8	38594

are in compliance with the Essential Requirements as defined by the provisions of Council Directive 93/42/EEC. The above listed medical devices have been classified according to the classification rules and have met all the applicable conformity assessment elements.
The conformity assessment procedure has been applied according to Council Directive 93/42/EEC Annex II. Applied harmonized standards are listed in the essential requirements checklist of the medical devices.

This Declaration of Conformity is valid until March 2016

Notified Body: TÜV SÜD Product Service GmbH, D- 80339 Munich
Identification number 0123

Basel, 2011-03-16

Head Corp. Regulatory Affairs
Toni Joergensen

Head of Corp. Qual.Design&Product Compliance
Patrick Sauder

The annexes of Directive 93/42/ECC form a constituent part of this declaration. While this declaration certifies conformity with the specified Directives, it does not serve as guarantee of properties in the context of product liability legislation. The comments in the supplied product documentation should be observed.