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CE 0123

Declaration of conformity

Manufacturer Address	Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan Liechtenstein
Product	**SpeedCEM®** **SpeedCEM® Plus**
Type of material	Self-adhesive self-curing dental resin cement with light-curing option
Product category	Cements
Classification	Medical Device Class IIa

We hereby declare under our exclusive responsibility that the above mentioned products meet the provisions of the following EC Council Directives and its implementation in national law. All supporting documentation is retained on the premises of the manufacturer and the notified body.

Directives	Medical Device Directive 93/42/EEC, Annex II. 3
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Deutschland
Place, Valid from	Schaan, 2015-12-18 Replaces version of: 2015-06-23
Valid until	2020-12-10

Signature		
Name Position	Dr. Thomas Hirt CTO	Dipl. Ing. Patrik Oehri Director CQM and Regulatory Sicherheitsbeauftragter (Product Safety Officer)
Date	2015-12-18	2015-12-18

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Attachment to Declaration of conformity

Product	**SpeedCEM®** **SpeedCEM® Plus**
Dated	2015-12-17

627589	SpeedCEM Starter Pack transparent
627590	SpeedCEM Refill transparent
627591	SpeedCEM Refill yellow
627592	SpeedCEM Refill opaque
681709	SpeedCEM Plus Test Pack transp. 2.5g
681710	SpeedCEM Plus Refill gelb 9g
681711	SpeedCEM Plus Refill opak 9g
681712	SpeedCEM Plus Refill transp. 9g
681713	SpeedCEM Plus Starter Pack trans. 2.5g
681714	SpeedCEM Plus System Kit trans. 9g
681715	SpeedCEM Plus Sample Pack trans. 2.5g
682339	SpeedCEM Plus Promo Pack

Place, Valid from	Schaan, 2016-02-04 Replaces version of: 2015-12-18	
Signature		
Name Position	Dr. Erik Braziulis Scientific Service, R&D	Sandra Cakebread Regulatory Affairs, R&D
Date	2016-02-04	2016-02-04

This Declaration of Conformity is handled without the suffix "AN", "EN", "AL", "WW" etc after the article number. The suffix is only for in-house reference and relates to the language version (e g. English, Spanish, French, etc) and/or electrical plug of the product. The suffix does not belong to the official article number.