

## EU Declaration of Conformity for Class\_IIa\_247532697


Document Information (OTCS)	
OTCS – Doc.-ID	247532697
Version	1.0

Signatures	
Author(s)	The signatures of all involved signatories are added on the last page of this document.
Reviewer(s)	
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## Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

We hereby declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer and the below mentioned products meet the provisions of the EU Regulation above. All supporting documentation is retained on the premises of the manufacturer and the Notified Body.

<b>Device under Assessment or Product(s)</b>	<b>Speedcem Plus Multilink Speed Speedcem 100</b>
<b>Basic-UDI-DI</b>	76152082ACEME002DX

Legal manufacturer	
	Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan/Liechtenstein www.ivoclar.com

EU Declaration of Conformity Information	
<b>SRN</b>	LI-MF-000000522
<b>Intended Purpose</b>	Self-adhesive cementation of indirect anterior and posterior restorations
<b>Category (MDCG 2019-14)</b>	MDN 1103 Non-active dental implants and dental materials
<b>EMDN Code + term</b>	Q0101010201 Dental Base Cements
<b>MDS Code</b>	MDS 1007
<b>MDT Code</b>	MDT 2006 MDT 2011
<b>EU Risk Classification (MDR Annex VIII)</b>	Medical Device Class IIa <b>CE 0123</b>
<b>Conformity Assessment Procedure (MDR Annex IX)</b>	<input checked="" type="checkbox"/> Quality Management System <input type="checkbox"/> Assessment of the Technical Documentation
<b>Notified Body Address</b>	<b>TÜV SÜD Product Service GmbH</b> Ridlerstrasse 65 80339 München Deutschland
<b>EC Certificate No.</b>	G10 043306 0270 Rev. 01
<b>Valid until</b>	2026-05-04

## Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
632342AN	Multilink Speed Refill transparent	Ila	8
681710WW	Speedcem Plus Refill gelb 9g	Ila	8
681711WW	Speedcem Plus Refill opak 9g	Ila	8
681712WW	Speedcem Plus Refill transp. 9g	Ila	8
692422WW	Speedcem Plus Refill 3x9g transp.	Ila	8
692423WW	Speedcem Plus Refill 3x9g yellow	Ila	8
701230WW	Speedcem 100 Refill 1x9g transparent	Ila	8

Document Revision History			
Version	Date	Author	Remark
1.0	2024-10-11	R. Ritter	First MDR Vesion

## Signing Page

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### Document Approval (OTCS)

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