EU 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.

Product	**X PLEX**
Basic-UDI-DI	763O81342APROS004VJ
Document-ID	OTCS212297370
Document Version	1.0

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EU Declaration of Conformity Information		
SRN	CH-MF-000015795	
Intended Purpose	Fabrication of bases for removable dentures	
Category (MDCG 2019-14)	MDN 1209	Non-active non-implantable dental materials
EMDN Code + term	Q010699	Materials for the preparation of custom-made dental devices - other
MDS Code	MDS 1007	
MDT Code	MDT 2006 MDT 2011	
EU Risk Classification (MDR Annex VIII)	Medical Device Class IIa CE 0123	
Conformity Assessment Procedure (MDR Annex IX)	☒ Quality Management System	
Notified Body Address	**TÜV SÜD Product Service GmbH** Ridlerstrasse 65 80339 München Deutschland	
MDR Certificate No.	☒ G20 090341 0017 Rev. 00	
Valid until	2028-11-02	

Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
709543	X PLEX 150ML MONOMER COLD	Class IIa	Rule 5, bullet 3
710657	X PLEX 150ML MONOMER HOT	Class IIa	Rule 5, bullet 3
709544	X PLEX 500ML MONOMER COLD	Class IIa	Rule 5, bullet 3
710658	X PLEX 500ML MONOMER HOT	Class IIa	Rule 5, bullet 3
710848	X PLEX 100G F34	Class IIa	Rule 5, bullet 3
710849	X PLEX 100G F53	Class IIa	Rule 5, bullet 3
710850	X PLEX 100G F55	Class IIa	Rule 5, bullet 3
710851	X PLEX 100G F57	Class IIa	Rule 5, bullet 3
710854	X PLEX 500G F1	Class IIa	Rule 5, bullet 3
710896	X PLEX 500G F3	Class IIa	Rule 5, bullet 3
710902	X PLEX 500G F34	Class IIa	Rule 5, bullet 3
710900	X PLEX 500G F5	Class IIa	Rule 5, bullet 3
710916	X PLEX 6 X 500G F34	Class IIa	Rule 5, bullet 3
710913	X PLEX 6 X 500G F5	Class IIa	Rule 5, bullet 3

Document Control			
Name	**Place of issue**	**Date of issue**	**Signature**
Approver (PRRC): Alexander Schwaszta	Glattpark, CH	2024-06-11	
Approver (Managing Director): Claudia Schenkel-Thiel	Glattpark, CH	2024-06-11	

Revision History			
Version	**Date**	**Author**	**Remark**
1.0	2024-06-10	Miriam Stange	First MDR Version