


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.

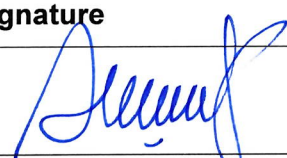

Product	X PLEX
Basic-UDI-DI	763081342APROS004VJ
Document-ID	OTCS212297370
Document Version	1.0

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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)	<input checked="" type="checkbox"/> Quality Management System
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Deutschland
MDR Certificate No.	<input checked="" type="checkbox"/> 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