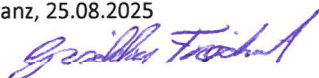


DoC - DECLARATION OF CONFORMITY					
CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM					
DOCUMENT NUMBER	1240-DOC-097	REVISION LEVEL	08	PAGE NO	Page 1 of 1

Manufacturer:	Dentsply DeTrey GmbH De-Trey-Str. 1 78467 Konstanz Germany Single registration number (SRN): DE-MF-00005905				
Authorized EU-representative:	N/A				
Authorized UK-representative:	Dentsply IH Ltd. Brunel Way Stonehouse Gloucestershire GL10 3GB United Kingdom				
PRODUCT CODE / CATALOGUE NUMBER			NAME		
606.67.347			Prime&Bond active Intro Kit		
606.67.340			Prime&Bond active Mini Refill		
606.67.341			Prime&Bond active Standard Refill		
606.67.342			Prime&Bond active Eco Refill		
606.67.348			Prime&Bond active Bottle Sample		
606.67.349			Prime&Bond active Risk Free		
606.67.343			Prime&Bond active 80 SUD Refill		
606.67.344			Prime&Bond active SUD Sample		
606.67.345			Prime&Bond active SUD Eco Refill		
606.67.353			Prime&Bond active 50 SUD Refill		
606.67.354			Prime&Bond active 100 SUD Refill		
606.67.351			Prime&Bond universal Mini Refill		
606.67.350			Prime&Bond universal Standard Refill		
606.67.352			Prime&Bond universal Sample (not for regular sale)		
Classification and Rules (EU)	EU class: The medical Devices are classified as Class IIa according to Rule 8 of Annex IX, MDD				
Basic UDI-DI :	++D010ADH02ME				
EMDN code / description :	Q01010104, Dental Restorative Materials, Adhesives				
GMDN code / description :	34782, Dental Restorative Materials, Adhesives				
Intended purpose:	Dental adhesive for tooth substrates and primer for restorative materials.				
WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF - THE COUNCIL DIRECTIVE 93/42/EEC AMENDED BY 2007/47/EC FOR MEDICAL DEVICES, IN ACCORDANCE WITH THE ANNEX II excluding 4. - ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. - THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.					
External references applied	N/A				
EC Certificate	G1 021108 0031 Rev. 00 TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Germany ID number of NB: 0123				
UK Certificate	N/A				

Konstanz, 25.08.2025



Grischka Friedrich,
Senior Manager QA

FORM NO	8000-FM-008-05	REVISION LEVEL	6
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