

DoC - DECLARATION OF CONFORMITY



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

DOCUMENT NUMBER	1240-DOC-097	REVISION LEVEL	07	PAGE NO	Page 1 of 1
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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. The Heights Building 3 Weybridge KT13 ONY 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, 17.01.2024

 Grischka Friedrich,
 Senior Manager Quality Assurance & Regulatory
 Compliance