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