



Document Detail

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Title: Prome & Bond NT Light Cured and Prime & Bond NT Dual Cure - Declaration of Conformity
Comment:
Status: CURRENT
Effective Date: 31-Jul-2023

Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
0070-Document Control Milford Document Control	Michelle Wilson	20-Jul-2023 3:17 pm	GMT
0070-RA Approver Milford Regulatory Affairs Approver	Stacia Preston	31-Jul-2023 2:18 pm	GMT

PRIME&BOND® NT NANO-TECHNOLOGY DENTAL ADHESIVE
DoC - DECLARATION OF CONFORMITY



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

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Manufacturer:	Dentsply LLC, also trading as DENTSPLY Caulk 38 West Clarke Avenue, Milford DE 19963 USA Single Registration Number (SRN): US-MF-000016555
Authorized EU-representative:	Dentsply DeTrey GmbH, De-Trey-Strasse 1, 78467 Konstanz, Germany Single Registration Number (SRN): DE-AR-000005904
Authorized UK-representative:	N/A
PRODUCT CODE / CATALOGUE NUMBER	NAME
634350	Prime&Bond® NT Nano-Technology Dental Adhesive Introductory Kit
634352	Prime&Bond® NT Nano-Technology Dental Adhesive Refill Package
634356	Prime&Bond® NT Nano-Technology Dental Adhesive Unit Dose Package
Classification and Rules (EU and UK)	EU class: Class IIa following Rule 8, long term, invasive, implantable device ACCORDING TO ANNEX IX Section III UK Class: N/A
Basic UDI-DI	++D002ADHESIVESBONDINGQ2
EMDN code / description :	Q01010104 Dental Bonding Agents
GMDN code / description :	34782 Dentine bonding agent/set
Intended purpose :	Prime&Bond® NT Nano-Technology Total-Etch Dental Adhesive System is designed to bond composite and compomer materials to enamel and dentin as well as to metals and ceramic.
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 ANNEX I ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.	
External reference applied	See TF035-CL
EC Certificate:	CE668748 BSI Group the Netherlands Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Notified Body identification number 2797
UK Certificate	N/A
Reference to the corresponding Technical Documentation	TF035

Dentsply LLC, also trading as DENTSPLY Caulk
 38 West Clarke Avenue
 Milford DE 19963
 USA


 Stacia Preston
 Regulatory Affairs Manager

7/19/23
 Date

FORM NO	8000-FM-008-05	REVISION LEVEL	5
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