For better dentistry®

DENTSPLY
CAULK

L.D. Caulk Division
38 West Clarke Avenue
Milford, DE 19963-1805
(302) 422-4511

Prime & Bond® NT™

EC Declaration of Conformity

Manufacturer's Name Address:	DENTSPLY Caulk 38 West Clarke Avenue Milford DE 19963 USA
Authorized EC Representative Name and Address:	DENTSPLY DeTrey GmbH D-78467 Konstanz Germany

Unique Product Identification:

634350	Prime & Bond® NT™ Nano-Technology Light Cured Dental Adhesive System Introductory Kit
634350-6	Prime & Bond® NT™ Nano-Technology Light Cured Dental Adhesive System Introductory Bulk Kit
634352	Prime & Bond® NT™ Nano-Technology Light Cured Dental Adhesive System Refill Package
635352-6	Prime & Bond® NT™ Nano-Technology Light Cured Dental Adhesive System Refill Bulk Package
634351	Prime & Bond® NT™ Nano-Technology Light Cured Dental Adhesive System Economy Package
634351-6	Prime & Bond® NT™ Nano-Technology Light Cured Dental Adhesive System Economy Bulk Package
634356	Prime & Bond® NT™ Nano-Technology Light Cured Dental Adhesive System Unit Dose Package
634353	Prime & Bond NT Dual Cure Nano-Technology Universal Dental Adhesive System

Description:

Prime&Bond® *NT*™ Adhesive - is a light cure self-priming dental adhesive designed to bond light cured composite and compomer materials to enamel and dentin as well as to metals and ceramic. Prime&Bond® *NT*™ Adhesive combines primer and adhesive in a single container. The reduction of components and treatment steps simplifies use, maintaining superior bond strengths and protection against microleakage. Prime&Bond® *NT*™ Adhesive is available in a 4.5 ml tri-laminated bottle and in pre-dosed, 0.125 ml disposable containers for single patient use.

Prime&Bond® *NT*™ Dual Cure - is a universal self-priming dental adhesive system designed to bond composite and compomer materials to enamel and dentin as well as to metals and ceramic. The reduction of components and treatment steps simplifies use, maintaining superior bond strengths and protection against microleakage.

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GMDN Code: 42483 – Dentine adhesive

Product Classification Per Annex IX: This product is classified as a Class IIa Medical Device under Annex IX Section III, rule 8, long term, invasive, implantable device.

EC Declaration of Conformity:

The above listed medical device(s) conform to the requirements of Council Directive 93/42/EEC *as amended by Council Directive 2007/47/EC* and meet the relevant Essential Requirements of Annex I. All devices are designed, manufactured, tested, and released for sale in accordance with the technical documentation.

This declaration is made on the basis of the Certificate of Conformity US97/10442 issued by SGS United Kingdom Ltd. Systems & Services Certification with Notified Body identification number 0120 in accordance with Annex VII of the Directive.

DENTSPLY Caulk Division maintains a quality management system that complies with the United States Food and Drug Administration 21 CFR Parts 820 & 211, ISO 13485:2003, CMDR, JPAL (MO 169) and the European Union Council Directive 93/42/EEC

Authorized Signature:

Name: RSC
Rebeca Santiago
QA/RA Manager

Date of Issuance: 10/11/11