



Document Detail

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Title: Core-X Flow Declaration of Conformity
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Effective Date: 07-Oct-2022

Approval

| <u>Owner Role</u> | <u>Sign-off By</u> | <u>Sign-off Date</u> | |
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| 0070-Document Control Milford Document Control | Michelle Wilson | 06-Oct-2022 6:45 pm | GMT |
| 0070-RA Approver Milford Regulatory Affairs Approver | Stacia Preston | 07-Oct-2022 1:48 pm | GMT |

**CORE•X® FLOW DUAL CURE CORE BUILD-UP MATERIAL AND
CEMENT FOR ENDODONTIC POSTS
DoC - DECLARATION OF CONFORMITY**

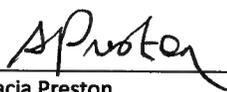


CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

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| RECORD NUMBER | MILFORD 0070-TF046-DOC-3 | REVISION LEVEL | 13 | PAGE NO | Page 1 of 1 |
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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 |
| 606.67.330 | core•X™ flow Dual Cure Build-Up Material and Cement for Endodontic Posts Syringe Refill |
| Classification and Rules (EU and UK) | EU class: Class IIa following Rule 8, long term, implantable, invasive device ACCORDING TO ANNEX IX Section III |
| Basic UDI-DI | ++D002DENTALCOMPOSITES68 |
| Intended purpose: core•X™ Flow Dual Cure Core Build-up Material and Cement for Endodontic Posts consists of two components, base plus catalyst, which when mixed form a dual-cured, highly filled, composite resin core build-up material. | |
| 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. | |
| Common Specifications applied: | N/A |
| Technical Standards ref.: | N/A |
| 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 | TF046 |
| Expiration date for the DoC | N/A |

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Stacia Preston
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10/4/22
Date