Document Detail

Type: 0070-Tech File DOC

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Title: Self Cure Activator Declaration of Conformity

Comment:

Status: CURRENT

Effective Date: 26-Aug-2022

Approval

Owner Role	Sign-off By	Sign-off Date	
0070-Document Control Milford Document Control	Michelle Wilson	25-Aug-2022 6:11 pm	GMT
0070-RA Approver Milford Regulatory Affairs Approver	Stacia Preston	26-Aug-2022 3:36 pm	GMT

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**
634354	Self Cure Activator Refill Package
634354K	Self Cure Activator Refill Package
Classification and Rules (EU and UK)	EU class: Class IIa Rule 8 long term, invasive, implantable device ACCORDING TO ANNEX IX Section III UK Class: N/A
Basic UDI-DI	++D002ADHESIVESBONDINGQ2
Intended purpose: Self Cure Activator is designed to be used with Prime&Bond® NT™ Nano-Technology Total-Etch Dental Adhesive System and Xeno® IV Self-Etching Dental Adhesive to create universal self-priming dental adhesive systems compatible with DENTSPLY manufactured dual cure/self-cure resin cements to bond indirect restorations and endodontic posts.	
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	TF035
Expiration date for the DoC	N/A

Dentsply LLC, also trading as
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SPreston 8/24/22

Stacia Preston — Date
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