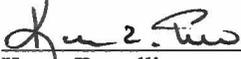


DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC

Manufacturer:	Dentsply LLC, also trading as DENTSPLY Caulk 38 West Clarke Avenue, Milford DE 19963 USA		
Design Holder:	Dentsply LLC, also trading as DENTSPLY Caulk 38 West Clarke Avenue, Milford DE 19963 USA		
Authorized EU-Representative:	DENTSPLY DeTrey GmbH, DeTrey Strasse 1, Konstanz Germany D-78467		
Unique Product Identification:	NAME	Classification	Rule
624075	Enhance® Finishing System Complete System Kit	IIa	5
624045X	Enhance® Finishing System Disc Refill Package	IIa	5
624045X-6	Enhance® Finishing System Disc Refill Package (6 Pack)	IIa	5
624055X	Enhance® Finishing System Cup Refill Package	IIa	5
624055X-6	Enhance® Finishing System Cup Refill Package (6 Pack)	IIa	5
624065X	Enhance® Finishing System Point Refill Package	IIa	5
624065X-6	Enhance® Finishing System Point Refill Package (6 Pack)	IIa	5
624040	Enhance® Finishing System Sample	IIa	5
624345	Enhance® mini Finishing System - Finishing Disc Refill	IIa	5
624355	Enhance® mini Finishing System - Finishing Cups Refill	IIa	5
624365	Enhance® mini Finishing System - Finishing Points Refill	IIa	5
624375	Enhance® mini Finishing System - Sample	IIa	5
624385	Enhance® mini Finishing System - Introductory Kit	IIa	5
662010Y	enhance® PoGo® Disc Refill - Export Package	IIa	5
662010Y-6	enhance® PoGo® Disc Refill - Export Package (6 Pack)	IIa	5
662022Y	enhance® PoGo® Point Refill - Export Package	IIa	5
662022Y-6	enhance® PoGo® Point Refill - Export Package (6 Pack)	IIa	5
662023Y	enhance® PoGo® Cup Refill - Export Package	IIa	5
662023Y-6	enhance® PoGo® Cup Refill - Export Package (6 Pack)	IIa	5
662025Y	enhance® PoGo® Cup, Disc and Points Refill - Export Package	IIa	5
662025Y-6	enhance® PoGo® Cup, Disc and Points Refill - Export Package (6 Pack)	IIa	5
662020	enhance® PoGo® Complete Kit	IIa	5
662024	enhance® PoGo Sample Package	IIa	5
GMDN Code:	35807 Dental Abrasive Disk		
Classification Rules according to:	These products are classified as a Class IIa Medical Device under Annex IX Section III rule 5.		
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 I. All supporting documentation is retained under the premises of the manufacturer. The manufacturer is exclusively responsible for the Declaration of Conformity.			
Harmonized Standards applied:	Dentsply LLC, also trading as DENTSPLY Caulk maintains a quality management system that fully complies with the United States Food and Drug Administration 21 CFR Part 820 & 211, ISO 13485:2016, CMDR, PMDA (MO 169), ANVISA, TGA, and the European Union Council Directive 93/42/EEC.		
Technical Standards referenced:	Standard	Title	Compliance
	BS ISO 14971	Medical Devices - Application of Risk Management to Medical Devices	Full
	ISO 7405	Preclinical evaluation of the biocompatibility of medical devices used in dentistry – Test methods	Full
	ISO 10993-1	Biological Evaluation of medical devices – Part 1: Guidance on selection of tests	Full
	ISO 15223-1	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied.	Full
	BS EN 1641	Dentistry -- Medical devices for dentistry – Materials	Full

EC Certificate:	This declaration is made on the basis of the Certificate of Conformity CE 668748 issued by BSI Group The Netherlands, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands with Notified Body identification number 2797 in accordance with Annex II excluding section 4 of the Directive.
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Dentsply LLC, also trading as
DENTSPLY Caulk
38 West Clarke Avenue
Milford DE 19963
USA

 12 September 2019

Karen Trovalli Date
QA/RA Manager