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:	Dentsply IH Limited Brunel Way Stonehouse, Gloucestershire, GL10 3GB
PRODUCT CODE / CATALOGUE NUMBER	**NAME**
624040	Enhance® Finishing System Sample
624045	Enhance® Finishing System Disc Refill Package
624045X	Enhance® Finishing System Disc Refill Package (Export Only)
624055	Enhance® Finishing System Cup Refill Package
624055X	Enhance® Finishing System Cup Refill Package (Export Only)
624065	Enhance® Finishing System Point Refill Package
624065X	Enhance® Finishing System Point Refill Package (Export Only)
624075	Enhance® Finishing System Complete System Kit
624345	Enhance® mini Finishing System - Finishing Disc Refill
624355	Enhance® mini Finishing System - Finishing Cups Refill
624365	Enhance® mini Finishing System - Finishing Points Refill
624375	Enhance® mini Finishing System Sample
624385	Enhance® mini Finishing System Introductory Kit
662010	Enhance® PoGo® Polishing System Disc Refill Package
662010Y	Enhance® PoGo® Polishing System Disc Refill Package - Export
662020	Enhance® Finishing System and Enhance® PoGo® Polishing System Complete Kit
662022	Enhance® PoGo® Polishing System Point Refill Package
662022Y	Enhance® PoGo® Polishing System Point Refill Package - Export
662023	Enhance® PoGo® Polishing System Cup Refill Package
662023Y	Enhance® PoGo® Polishing System Cup Refill Package - Export
662024	Enhance® PoGo Polishing Sample Package
662025Y	Enhance® PoGo® Polishing System Refill Package (Cups, Discs, and Points) - Export
Classification and Rules (EU and UK)	EU / UK class: Class IIa following Rule 19 - device incorporates or consists of nanomaterial with negligible potential for internal exposure, and Rule 5 – transient, invasive device connected to an active device ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745 ACCORDING TO ANNEX IX OF THE DIRECTIVE 93/42/EC AND UK MDR 2002
Basic UDI-DI	++D002DENTALROTARYINSTR7F
EMDN code / description	Q0105 - Instruments for Dentistry, Single-Use
GMDN code / description	64617 - Dental abrasive disk, single-use
Intended purpose	Enhance & Enhance mini Finishers are indicated for contouring and finalizing the form of composite and compomer restorations. Enhance PoGo Polishers are indicated as the final step in polishing all properly contoured and finished composite resin and compomer restorations.

WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF

- THE REGULATIONS EU/2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX IX CHAPTER 1 AND III.
- UKMDR2002: THE MEDICAL DEVICE REGULATIONS 2002 (SI 618) as subsequently amended by the EU EXIT REGULATIONS OF 2019 (SI 791) and 2020 (SI 1478) WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN UK MDR PART II ANNEX II Sec. 3.2 Full Quality System.

ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

External references (Common Specifications, Standards, Regulations) applied:	TF016-LAER
EC Certificate:	MDR 744246 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	Technical Documentation Name: Enhance, Enhance mini, Enhance PoGo, Prisma Gloss Polishing Cups, and Metal Mandrels (for use with Prisma Gloss Polishing Cups) Technical Documentation Index: TF016-TDI

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

SPreston 4/23/25

Stacia Preston — Date
Regulatory Compliance Manager