



## Document Detail

---

**Type:** 0070-Tech File DOC  
**Document No.:** 0070-TF015-DOC-1[15]  
**Title:** Prisma Gloss Composite Polishing Paste System, Polishing Cups and Metal Mandrels DOC  
**Comment:**  
**Status:** CURRENT  
**Effective Date:** 03-Mar-2025

## Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
0070-Document Control Milford Document Control	Michelle Wilson	03-Mar-2025 8:54 pm	GMT
0070-RA Approver Milford Regulatory Affairs Approver	Stacia Preston	03-Mar-2025 9:42 pm	GMT

**PRISMA® GLOSS™ COMPOSITE POLISHING PASTE  
DoC - DECLARATION OF CONFORMITY**



**CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM**

<b>RECORD NUMBER</b>	MILFORD 0070-TF015-DOC-1	<b>REVISION LEVEL</b>	15	<b>PAGE NO</b>	Page 1 of 2
----------------------	--------------------------	-----------------------	----	----------------	-------------

<b>Manufacturer:</b>	Dentsply LLC, also trading as DENTSPLY Caulk 38 West Clarke Avenue, Milford DE 19963 USA Single Registration Number (SRN): US-MF-000016555
<b>Authorized EU-representative:</b>	Dentsply DeTrey GmbH De-Trey-Strasse 1, 78467 Konstanz, Germany Single Registration Number (SRN): DE-AR-000005904
<b>Authorized UK-representative:</b>	N/A
<b>PRODUCT CODE / CATALOGUE NUMBER</b>	<b>NAME</b>
624005	Prisma® Gloss™ Composite Polishing Paste System – Refill Package
631400	Prisma®• Gloss™ Composite Polishing Paste System Standard Package – Fine - 1 Syringe
631450	Prisma®• Gloss™ Composite Polishing Paste System Standard Package –ExtraFine - 1 Syringe
<b>Classification and Rules (EU and UK)</b>	EU class: Class IIa following Rule 19 - device incorporates or consists of nanomaterial with negligible potential for internal exposure and Rule 5 – transient, invasive device ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745 UK Class: N/A ACCORDING TO ANNEX IX OF THE DIRECTIVE 93/42/EC AND UK MDR 2002
<b>Basic UDI-DI</b>	++D002POLISHMATERIALKQ
<b>EMDN code / description</b>	Q01010403 - Dental Abrasive and Polishing Materials
<b>GMDN code / description</b>	11168 - Dentifrice
<b>Intended purpose</b>	Prisma® Gloss™ Composite Polishing Pastes are designed for final polishing of direct or indirect anterior and posterior composite resin restorative materials.
<p>WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF</p> <ul style="list-style-type: none"> <li>- THE REGULATIONS EU/2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX IX CHAPTER 1 AND III.</li> <li>- THE MEDICAL DEVICE REGULATIONS 2002 (SI 618) as subsequently amended by the EU EXIT REGULATIONS OF 2019 (SI 791) and 2020 (SI 1478).</li> </ul> <p>ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.</p>	
<b>External references (Common Specifications, Standards, Regulations) applied:</b>	TF015-LAER
<b>EC Certificate:</b>	MDR 744246 BSI Group the Netherlands Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Notified Body identification number 2797
<b>UK Certificate</b>	N/A
<b>Reference to the corresponding Technical Documentation</b>	Technical Documentation name: Prisma Gloss Technical Documentation Index: TF015-TDI

