

For better dentistry®

**DENTSPLY**  
CAULK

**L.D. Caulk Division**  
38 West Clarke Avenue  
Milford, DE 19963-1805  
(302) 422-4511

**Prisma® • Gloss™ Composite Polishing Paste System,**  
**Polishing Cups and Metal Mandrels**

**EC Declaration of Conformity**

**Manufacturer's Name** DENTSPLY Caulk  
**Address:** 38 West Clarke Avenue  
Milford DE 19963  
USA

**Authorized EC Representative** DENTSPLY DeTrey GmbH  
**Name and Address:** D-78467  
Konstanz Germany

**Unique Product Identification:** 624005 Prisma® Gloss™ Composite Polishing Paste System – Refill Package  
631400 Prisma® • Gloss™ Composite Polishing Paste System Standard Package – Fine - 1 Syringe  
631400-4 Prisma® • Gloss™ Composite Polishing Paste System Standard Package – Fine- 4 Syringes  
631450 Prisma® • Gloss™ Composite Polishing Paste System Standard Package –ExtraFine - 1 Syringe  
631450-4 Prisma® • Gloss™ Composite Polishing Paste System Standard Package –ExtraFine 4 Syringes

**Description:** Prisma®•Gloss™ Composite Polishing Pastes are water-soluble, aluminum oxide pastes designed for final polishing of anterior and posterior composite restorations, diastema closures, esthetic incisal lengthening's or veneers.

**GMDN Code:** 34771 - Dental coating, resin-filling surface

**Product Classification** This product is classified as a Class I Medical Device under Annex IX Section III, rule 5,  
**Per Annex IX:** transient invasive device.

**Unique Product Identification:** 624020 Polishing Cups Refill  
624025 Metal Mandrels for Prisma® Gloss™ Polishing Cups

**Description:** Prisma®•Gloss™ Composite Polishing Paste System includes water-soluble, aluminum oxide pastes designed for final polishing of anterior and posterior composite restorations, diastema closures, esthetic incisal lengthening's or veneers. When applied with the Prisma® Gloss™ Foam Polishing Cup, Prisma® Gloss™ Polishing Paste improves the smoothness of the finished surface of microfil composites to a final, high luster surface, or pre-polishes by smoothing finished surfaces of hybrid and micro-hybrid composites to low luster. For hybrid and micro-hybrid composites, following with Prisma® Gloss™ Extra Fine Polishing Paste results in a final, high luster polished surface.

**GMDN Code:** 35170 - Dental Mandrel

**Product Classification** This product is classified as a Class IIa Medical Device under Annex IX Section III rule 5  
**Per Annex IX:** transient invasive, connected to active medical device.

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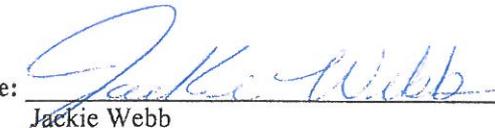
**EC Declaration of Conformity:**

The above listed medical device(s) conform to the requirements of Council Directive 93/42/EEC as amended by Council Directive 2007/47/EC and meet the relevant Essential Requirements of Annex I. All devices are designed, manufactured, tested, and released for sale in accordance with the technical documentation.

This declaration is made on the basis of the Certificate of Conformity US97/10442 issued by SGS United Kingdom Ltd. Systems & Services Certification with Notified Body identification number 0120 in accordance with Annex VII of the Directive.

DENTSPLY Caulk Division maintains a quality management system that complies with the United States Food and Drug Administration 21 CFR Parts 820 & 211, ISO 13485:2003, CMDR, JPAL (MO 169) and the European Union Council Directive 93/42/EEC

**Authorized Signature:**

Name:   
Jackie Webb  
Regulatory Assurance Specialist

Date of Issuance: 2-18-2015