



Déclaration de Conformité CE
EC Declaration of Conformity

<i>Manufacturer:</i>	PRODUITS DENTAIRE SA Rue des Bosquets 18 1800 Vevey Switzerland
<i>CHRN</i>	CHRN-MF-20000511
<i>SRN</i>	CH-MF-000023147

<i>European Authorized Representative</i>	PD Dental EU Rue des Arcouasses 4 Thonon-les-Bains, 74200 France
<i>European Authorized Representative SRN</i>	FR-AR-000017144

We declare under our sole responsibility that the medical device of the following Generic Device Group:

Ciments d'obturation à l'hydroxyde de Calcium
Calcium Hydroxide dental filling materials

<i>Reference:</i>	See attached table
<i>Risk class:</i>	IIa
<i>As per rule:</i>	7, Annex IX, Directive 93/42/EEC
<i>Intended Purpose:</i>	Opacal is intended for temporary root canal dressing (less than 30 days).
<i>Trade name:</i>	OPACAL
<i>Basic UDI-DI:</i>	764015916CA(OH)2YJ
<i>EMDN</i>	Q01010201 - Root canal filling dental pastes
<i>MDN Code</i>	MDN 1209 – Non-active non-implantable dental materials
<i>Conformity assessment procedure:</i>	<i>Directive 93/42/EEC Annex II (excluding section 4) + MDR extension Letter_ICIM contract n. 150931-155597/25</i>
<i>Registered with:</i>	SGS Belgium NV (Notified Body 1639) SGS House - Noorderlaan 87 2030 Antwerp Belgium
<i>EC certificate number:</i>	CH19/0994



Déclaration de Conformité CE
EC Declaration of Conformity

Validity **31.12.2028**

Quality & Compliance
Manager

Silvia Contini

Vevey, 2025-02-14

References Covered By This Declaration:

Reference	GTIN	Designation
11020	07640159161639	OPACAL, Calcium Hydroxide paste, 3 ml Syringe + 10 applicator tips
11022	07640159163015	OPACAL APPLICATOR TIPS, accessory for Opacal, pouch of 10 applicator tips