Déclaration de Conformité CE
EC Declaration of Conformity

Manufacturer:	PRODUITS DENTAIRES SA Rue des Bosquets 18 1800 Vevey Switzerland
CHRN	CHRN-MF-20010610
SRN	CH-MF-000023147

European Authorized Representative	PD Dental EU Rue des Arcouasses 4 Thonon-les-Bains, 74200 France
European Authorized Representative SRN	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

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

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Validity ***31.12.2028***

Regulatory Affairs Specialist / Alternate PRRC — Mélissa MOUA

Vevey, 2026-05-29

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**

The Declaration of Conformity has been updated from the Declaration of Conformity v4 signed and validated before 26 May 2021 for the extension period for Class IIa devices.

Version	Author	Changes
V05	Silvia Contini	Update to the declaration of conformity to incorporate the ICIM extension letter. Change of notified body.
V06	Mélissa Moua	Change to the CHRN number following the change to the VAT number of Produits Dentaires SA. Incorporation of a change history for our MDD CE declarations of conformity.