

### Déclaration de Conformité CE **EC Declaration of Conformity**

PRODUITS DENTAIRES SA Manufacturer:

Rue des Bosquets 18

1800 Vevey Switzerland

**CHRN** CHRN-MF-20000511 SRN CH-MF-000023147

European Authorized

PD Dental EU Representative

Rue des Arcouasses 4 Thonon-les-Bains, 74200

France

European Authorized

FR-AR-000017144 Representative SRN

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

#### Mineral Based Dental Materials

#### Matériaux dentaires à base de minéraux

Reference: See attached table

Risk class: lla

As per rule: 8, Annex IX, Directive 93/42/EEC

PD MTA White is intended for local obturation and repairing of the root canal wall during Intended Purpose:

dental treatment.

Trade name: PD MTA White

Basic UDI-DI: 764015916MTAM4

**EMDN** Q01010102 Temporary and permanent dental restoration cements

MDN Code MDN 1103 – Non-active dental implants and dental material

Conformity assessment

Directive 93/42/EEC Annex II (excluding section 4) + MDR extension

Letter\_ICIM contract n. 150931/24 procedure:

SGS Belgium NV (Notified Body 1639)

SGS House - Noorderlaan 87

Registered with:

2030 Antwerp Belgium



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EC certificate number:

CH19/0994

Validity

31.12.2028

Quality & Compliance

Manager

Silvia Contini

Vevey, 2024-10-29

## References Covered By This Declaration:

Reference	GTIN	Designation
20190	07640159160014	PD MTA White, 4 sachets with 140 mg + pure Water 3 ml