

The management system of

Produits Dentaires SA

18 rue des Bosquets

CH-1800 Vevey

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

- MAP System Non sterile endodontic material placement instrument
- Non sterile Mineral based filling dental material
- Non sterile calcium hydroxide based dental filling material
- Non-sterile zinc oxide based dental cements for endodontic and restorative applications
- Non sterile dental fiber post
- Non sterile Dental desobturating material
- Non sterile endodontic cleaning and irrigation materials
- Non sterile dental Drills and reamers
- Non-sterile root canal irrigation cannulae.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 25 May 2021 until 8 June 2023 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 10 June 2012.

Certification is based on reports numbered CH/GE 3205871

Authorised by

Global Medical Devices Head of Notified Body

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LPMD5007 - Certificate CE1639 Annex II-4, EN rev. 02

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