EC Certificate Full Quality Assurance System: Certificate CH19/0994

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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