

EU Quality Management System Certificate CH24/00000115

The management system of

Produits Dentaires S.A.

18 Rue des Bosquets, 1800 Vevey, Switzerland

SRN Number: CH-MF-000023147

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 28 November 2024 until 28 November 2029 and remains valid subject to satisfactory surveillance audits.

Recertification audit due before 28 May 2029

Issue 1. Certified since 28 November 2024



Authorised by

Virginie Siloret

Global Medical Device

Certification Manager

SGS Belgium NV NB1639

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EU Quality Management System Certificate CH24/00000115,
continued

SGS

Produits Dentaires S.A.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I)

Class IIA devices

MDN 1208

Endodontic non-sterile root canal irrigation cannulae
[Basic UDI-DI: 764015916CANNULASXW]

MAP System - Non sterile endodontic material placement instrument
[Basic UD-DI: 764015916MAPSYSTEMYA]

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - CH/GE/4309317 - S2A 1.1 + TFR 1.3

Authorized representative name and address (if relevant): PD Dental EU, Rue des Arcouasses 4,
74200 Thonon les Bains, France

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

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