Produits Dentaires SA
Rue des Bosquets 18
1800 Vevey
Switzerland
Phone +41 21 921 26 31
Fax + 41 21 921 39 79
info@pd-dental.ch
www.pd-dental.ch

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Produits Dentaires SA
Manufacturer address and contact details	Rue de Bosquets 18, 1800 Vevey, Switzerland
Single Registration Number (SRN)	CH-MF-000023147

Authorised Representative name	PD Dental EU
Authorised Representative address and contact details	Rue des Arcouasses 4, 74200 Thonon-les-Bains, France
Single Registration Number (SRN)	FR-AR-000017144

Notified body name (if applicable)	SGS Belgium NV
Notified body number (if applicable)	CE 1639
Directive Certificate number(s) to which this confirmation is made (if applicable)	CH19/0994
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	08.06.2023
End date of extended validity/transition period	31.12.2028

We, as the manufacturer declare under our sole responsibility:

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- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate(s)** as listed above or in the attached schedule
  - Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.
  - Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- **Quality Management System (QMS)**
  - A QMS in accordance with Article 10(9) MDR is in place.
- **Device(s) as listed in the attached schedule**
  - The devices continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Produits Dentaires SA

Vevey, 26.09.2024 PRODUITS DENTAIRES S.A. CH-1800 VEVEY

Silvia Contini, Quality & Compliance Manager

regulatory@pd-dental.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**
Non-sterile root canal irrigation cannulae	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	SGS Belgium NV / CE 1639	31.12.2028
MAP System - Non sterile endodontic material placement instrument	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	SGS Belgium NV / CE 1639	31.12.2028

[1] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)