Produits Dentaires SA
Rue des Bosquets 18
1800 Vevey
Switzerland
Phone +41 21 921 26 31
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info@pd-dental.ch
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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	31.12.2027 or 31.12.2028 (See attached schedule of devices for more details)

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We, as the manufacturer declare under our sole responsibility:

- 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Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.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 PRODUITS DENTAIRES S.A. CH-1800 VEVEY

Vevey, 12.01.2024

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**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**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
EDTA - Non sterile endodontic cleaning and irrigation material	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	SGS Belgium NV / CE 1639	31.12.2028
MTA- Non sterile mineral based filling dental material	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	SGS Belgium NV / CE 1639	31.12.2028
Fibrapost - Non sterile dental fiber post	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)

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Opacal - Non sterile calcium hydroxide based dental filling material	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	SGS Belgium NV / CE 1639	31.12.2028
Eugenate Desobturator - Non sterile dental desobturating material	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	SGS Belgium NV / CE 1639	31.12.2028
Essenseal - Non sterile zinc oxide based dental cements for endodontic and restorative applications	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	SGS Belgium NV / CE 1639	31.12.2027
Zinc Oxide & Eugenol - Non sterile zinc oxide based dental cements for endodontic and restorative applications	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	SGS Belgium NV / CE 1639	31.12.2027

Produits Dentaires SA
8 rue des Bosquets
1800 Vevey
Switzerland

May 7th, 2024

Confirmation Letter Reference: CLNB1639 - CH/GE 3205871

To whom it may concern,

Confirmation of receipt of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer

Produits Dentaires SA
18 rue des Bosquets
1800 Vevey
Switzerland
SRN Number (if available):

PD Dental EU
Rue des Arcouasses 4
74200 Thonon les Bains
France
The SRN Number: FR-AR-000017144

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV NB1639,

Ian How
PP
Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive**:**

Device name or Basic UDI-	**MDR Device classification**	**MDD Device name**	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device (	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Irrigation Cannula: The device is a flexible cannula with radial opening for liquid ejection along the dental root canal walls. 764015916CANNULASXW	Class IIa	Irrigation Cannula	N/A	Certificate CH19/0994 / NB1639
MAP System: Non sterile endodontic material placement instrument 764015916MAPSYSTEMYA	Class IIa	MAP System	N/A	Certificate CH19/0994 / NB1639
Opacal: Non sterile calcium hydroxide paste for temporary root canal dressing as part of endodontic treatment 764015916CA(OH)2YJ	Class IIa	Opacal	N/A	Certificate CH19/0994 / NB1639
EDTA: Non sterile endodontic cleaning and irrigation material 764015916EDTADF	Class IIa	EDTA	N/A	Certificate CH19/0994 / NB1639
PD MTA White: Non sterile mineral based filling dental material 764015916MTAM4	Class IIa	PD MTA White	N/A	Certificate CH19/0994 / NB1639
Eugenate Desobturator: Non sterile dental desobturating material 764015916EUGENATE3J	Class IIa	Eugenate Desobturator	N/A	Certificate CH19/0994 / NB1639
Fibrapost: Non sterile dental fiber post 764015916FIBRAPOSTS8E	Class IIa	Fibrapost	N/A	Certificate CH19/0994 / NB1639

Device name or Basic UDI-	**MDR Device classification**	**MDD Device name**	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device (	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Essenseal: Non sterile zinc oxide based dental cements for endodontic and restorative applications 764015916ESSENSEALSK	Class III	Essenseal	N/A	Certificate CH19/0994 / NB1639
Zinc Oxide & Eugenol: Non sterile zinc oxide based dental cements for endodontic and restorative applications 764015916EUGENOLPW 764015916ZINCOXIDE29	Class III	Zinc Oxide & Eugenol		Certificate CH19/0994 / NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/07	Version 1	Initial issue
2024/05/22	Version 2	Addition of devices: • MAP System • Opacal • EDTA • PD MTA White • Eugenate Desobturator • Fibrapost • Essenseal • Zinc Oxide & Eugenol to the list