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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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
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Global Medical Device Certification Manager
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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