Notified Body Confirmation Letter Reference: C689463

To whom it may concern,

Confirmation 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, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 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:

Premier Dental Products Company, Inc.
1710 Romano Drive
Plymouth Meeting, PA 19462

SRN Number (if available):

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

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 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

Place and date:
Høvik, 18.12.2024

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

- 26 May 2026 for Class III custom-made implantable devices
- 31 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)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 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)

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 and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Traxodent 00348783TraxodentQY 00348783Traxodent-ItenaRF	Class IIa	Traxodent® Hemodent Paste Retraction System (Same product but applied MDR with new 'product name')	Certificate number: 10000381176-PA-NA-NOR NB number NB: 2460
Premier® RC-Prep® Root Canal Preparation Cream 00348783RC-PrepMX	Class IIa	RC-Prep (Same product but applied MDR with new 'product name')	Certificate number: 10000381155-PA-NA-NOR Rev.0.0 NB number NB: 2460
PIC/PIC+ 00348783PICSG 00348783PICPlusXA	Class IIa	Premier Implant Cement (PIC) Premier Implant Cement Plus (PIC Plus) (Same product but applied MDR with new 'product name')	Certificate number: 10000381155-PA-NA-NOR Rev.0.0 NB number NB: 2460
Knit-Pak+ 300348783Knit-Pak+L9	Class IIa	Knit-Pak+ (Same product but applied MDR with new	Certificate number: 10000381155-PA-NA-NOR Rev.0.0 NB number NB: 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
		'product name')	
Hemodent 00348783HemodentBC	Class IIa	Hemodent	Certificate number: 10000381155-PA-NA-NOR Rev.0.0 NB number NB: 2460

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Dental Instruments Premier Elevator-00348783PremierElevatorQ7 Premier Periotome-00348783PeriotomeMC Premier Explorers-00348783ExplorersQ8 Premier Probes-00348783PremierProbes73 Premier Scalers-00348783PremierScalers83 Premier Curettes-00348783PremierCurettesWH Premier Cavity Prep-00348783CavityPrepJ8 Premier Excavators-00348783ExcavatorsMB Premier Applicators-00348783Applicators37 Premier Amalgam Carrier-00348783AmalgamCarrierV9 Premier Cord Packers-00348783CordPackersJJ Premier Pluggers-00348783PremierPluggersXD Premier Carvers-00348783PremierCarvers6S Premier Burnisher-00348783BurnisherKH Premier Knives-00348783PremierKnives5G	Class Ir	Premier Instruments (Same product but applied MDR with new 'product name')	Declaration of Conformity: DoC -Premier Instruments Rev.9_signed

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Premier Spreader-00348783PremierSpreaderWM Premier Composite Instruments-00348783CompositeIns5K Premier Spatula-00348783PremierSpatulaFW Premier File-00348783PremierFile7J Premier Lab Instruments-00348783LabInstrumentsLE Premier Crown Removers-00348783CrownRemovers9G Premier Mirror Handles-00348783MirrorHandles4Y Premier Retractors-00348783RetractorsWQ Premier X5 Sectional Matrix System-00348783PremierX5MatrixW3			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/06/13	C689463	Initial issue
2024/12/18	C689463	Updated to include Class Ir devices

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.