TÜV Rheinland Italia S.r.l.
Sicurezza e Qualità Prodotto

TÜV Rheinland Italia S.r.l.
Via Mattei 3
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Italia

Via del Faggiolo 1/12
40132 Bologna
Italia

Paltop Advanced Dental Solutions Inc.
Registered Headquarter:
154 Middlesex Turnpike
Burlington, MA 01803 (USA)

Attention:
Ms. Zina Gurgov

Date: 05/06/2024

Object: 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

Dear Ms. Gurgov

This letter confirms that, TUV RHEINLAND ITALIA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1936 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:

Paltop Advanced Dental Solutions Inc.
Registered Headquarter:
154 Middlesex Turnpike
Burlington, MA 01803 (USA)

The devices covered by the formal application and the written agreement mentioned above are identified in the Table below.
The table identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has already took the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry.

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EURO 51.000,00 int. versato
C.C.I.A.A. Milano No. 1535451
Registro Milano No. 214918
CF e IVA 12184570153

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:

- 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)

Devices covered by this letter, and for which the NB is responsible for appropriate surveillance of the corresponding devices under the applicable Directive, and identified on the basis of the indications provided in the MDR application received:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer)**	**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**
GROUP: Dental Impants **CATEGORY:** **Advance Dental Implant,** **Advanced+ Dental Implant,** **DIVA by Paltop Dental Implant,** **DIVA Screw,** **Dynamic Conical Dental Implant,** **Dynamic Dental Implant,** **PAI Dental Implant,** **PAI Total Coverage (TC) Dental Implant,** **PCA Dental Implant,** **Cover Screw**	Class IIb	N/A	Certificate issued by TUV RHEINLAND ITALIA Certificate no: HD 60149793 Annex II Date of issue 22/06/2020 Date of expiry 26/05/2024
GROUP: Prosthetics components **CATEGORY:** **PEEK Straight Concave Temporary Abutment,** **PEEK Angulated Concave Temporary Abutment,**	Class IIb, IIa, Is	N/A	Certificate issued by TUV RHEINLAND ITALIA Certificate no: HD 60149793 Annex II Date of issue 22/06/2020

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Cobalt Chrome Base Castable Abutment, **Straight Paltop Equator Abutment,** **Titanium Angulated Abutment,** **Titanium Anatomic Angulated Abutment,** **Titanium Anatomic Angulated Concave Abutment,** **Straight Ball Abutment,** **Titanium Straight Ball Abutment,** **Titanium Temporary Abutment,** **Titanium Single-Unit Cylinder,** **Titanium Multi-Unit Cylinder,** **Titanium Anatomic Straight Abutment,** **Titanium Anatomic Straight Concave Abutment,** **Titanium Angulated Multi-Unit Abutment,** **Titanium Straight Multi-Unit Abutment,** **Titanium Straight Single-Unit Abutment,** **Milling Blank Abutment,** **ACS Titanium Base Abutment,** **Titanium Base Abutment,** **Titanium Multi-Unit Interface Coping,** **Titanium Single- Unit Interface Coping,** **Titanium Retentive Multi-Unit Interface Coping,** **Snap-On Abutment System (SAS),** **Multi-Unit Screw,** **Abutment Screw,** **Angulation Corrective System Screw,** **Concave Healing Cap,** **Single-Unit Healing Cap,** **Straight Healing Cap,** **Multi-Unit Healing Cap,** **Concave Healing Cap,** **Straight Healing Cap,** **Plastic Snap-On Closed Tray Impression Coping,** **Gold Base Castable Abutment,** **Open Tray Impression Coping,** **Closed Tray Impression Coping,** **Open Tray Multi-Unit Impression Coping,** **Closed Tray Single-Unit Impression Coping,** **Open Tray Single-Unit Impression Coping,** **Closed Tray Multi-Unit Impression Coping,** **Multi-Unit Healing Cap Screw**			Date of expiry 26/05/2024

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Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer)**	**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**
GROUP:Surgical Instruments **CATEGORY:** **Pilot Drill Spade,** **Pilot Guided Drill Spade,** **Drill Extender,** **Final Drill,** **Fully Guided Drill,** **Pilot Guided Drill,** **Countersink,** **Guided Countersink,** **Tissue Punch,** **Hex Key,** **Bone Profiler Post Implant,** **Bone Profiler Pre-Implant,** **Insertion key,** **Step Drill Stop,** **Contra Angle Adaptor,** **Osteotome,** **Bone tap,** **Fully Guided Surgical Kit,** **Basic Complete Surgical Kit,** **Compact Surgical Kit,** **Premium Surgical Kit,** **Rapid Surgical Kit,** **Triangular Drill Stop Kit,** **Short Step Drill Kit** **Basic Osteotome Kit,** **Bone Profiler Post implant Kit,** **Countersink Kit,** **Bone Tap Kit,** **Wide Implant Drill Kit,** **Pilot Guided Drill Kit,** **Prosthetic Kit,** **Final Drill Stop,** **Drill Stop Kit,** **Step Drill,** **Osteotome Kit**	Class IIa	N/A	Certificate issued by TUV RHEINLAND ITALIA Certificate no: HD 60149793 Annex II Date of issue 22/06/2020 Date of expiry 26/05/2024
GROUP: Reusable Instruments (Ir) **CATEGORY:** **Fixation Pin,** **Pin Fixation for Full Guided Surgery,** **Pin Fixation Threaded,** **Angulated Indicator,** **Hand Piece Straight,** **Parallel Pin,** **Drill Depth Probe,**	Class Ir	N/A	N/A - Device did not require a Notified Body certificate under 93/42/EEC

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Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer)	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
Final Depth Pin, **Parallel Pin Kit,** **Bone Profiler Post Implant Pin,** **Stepped Depth Pin,** **Implant Body Try-In Kit**			

TUV RHEINLAND ITALIA (n.1936)

Cesare Gentile
Technical Manager

Annex: Certificate No. HD 60149793 issued by TÜV RHEINLAND ITALIA

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