

Dentatus AB

Finspångsgatan 42

SE- 163 53 Spånga

Sweden

2023-08-09

Notified Body Confirmation Letter**Reference: 41319232-03- CN00287-06**

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, Intertek Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2862 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:

Dentatus AB

Finspångsgatan 42

SE- 163 53 Spånga

Sweden

SRN Number: SE-MF-000021392

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 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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:

- 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)

On behalf of the Notified Body,



Brian Mather
Certification Manager
Intertek Medical Notified Body AB

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:

Ref Number/ Device Identification	Device Name	Device classification	MDD Certificate Reference(s)
SST-18	Surtext Posts/Stainless steel intro kit	Ila	41319232-03
SST-60	Surtext Post /Stainless steel starter refill-reamers	Ila	41319232-03
SST-B	Surtext Post / Stainless steel complete starter kit - reamers	Ila	41319232-03
SST	Surtext Posts /Stainless steel assortment – no reamers	Ila	41319232-03
SST-S1	Surtext Post Stainless Steel	Ila	41319232-03
SST-S2	Surtext Post Stainless Steel	Ila	41319232-03
SST-S3	Surtext Post Stainless Steel	Ila	41319232-03
SST-S4	Surtext Post Stainless Steel	Ila	41319232-03
SST-S5	Surtext Post Stainless Steel	Ila	41319232-03
SST-S6	Surtext Post Stainless Steel	Ila	41319232-03
SST-M1	Surtext Post Stainless Steel	Ila	41319232-03
SST-M2	Surtext Post Stainless Steel	Ila	41319232-03
SST-M3	Surtext Post Stainless Steel	Ila	41319232-03
SST-M4	Surtext Post Stainless Steel	Ila	41319232-03

SST-M5	Surtext Post Stainless Steel	Ila	41319232-03
SST-M6	Surtext Post Stainless Steel	Ila	41319232-03
SST-L1	Surtext Post Stainless Steel	Ila	41319232-03
SST-L2	Surtext Post Stainless Steel	Ila	41319232-03
SST-L3	Surtext Post Stainless Steel	Ila	41319232-03
SST-L4	Surtext Post Stainless Steel	Ila	41319232-03
SST-L5	Surtext Post Stainless Steel	Ila	41319232-03
SST-L6	Surtext Post Stainless Steel	Ila	41319232-03
SST-EL3	Surtext Post Stainless Steel	Ila	41319232-03
SST-EL4	Surtext Post Stainless Steel	Ila	41319232-03
SST-EL5	Surtext Post Stainless Steel	Ila	41319232-03
SST-EL6	Surtext Post Stainless Steel	Ila	41319232-03
SST-SL3	Surtext Post Stainless Steel	Ila	41319232-03
SST-SL4	Surtext Post Stainless Steel	Ila	41319232-03
SST-SL5	Surtext Post Stainless Steel	Ila	41319232-03
SST-SL6	Surtext Post Stainless Steel	Ila	41319232-03
RST-18	Surtext Posts Gold Plated intro kit	Ila	41319232-03
RST-60	Surtext Post Gold Plated assortment	Ila	41319232-03
RST-B	Surtext Post Gold Plated complete starter kit - reamers	Ila	41319232-03
RST	Surtext Posts Gold Plated assortment – no reamers	Ila	41319232-03
RST-S1	Surtext Posts Gold Plated	Ila	41319232-03

RST-S2	Surtext Posts Gold Plated	Ila	41319232-03
RST-S3	Surtext Posts Gold Plated	Ila	41319232-03
RST-S4	Surtext Posts Gold Plated	Ila	41319232-03
RST-S5	Surtext Posts Gold Plated	Ila	41319232-03
RST-S6	Surtext Posts Gold Plated	Ila	41319232-03
RST-M1	Surtext Posts Gold Plated	Ila	41319232-03
RST-M2	Surtext Posts Gold Plated	Ila	41319232-03
RST-M3	Surtext Posts Gold Plated	Ila	41319232-03
RST-M4	Surtext Posts Gold Plated	Ila	41319232-03
RST-M5	Surtext Posts Gold Plated	Ila	41319232-03
RST-M6	Surtext Posts Gold Plated	Ila	41319232-03
RST-L1	Surtext Posts Gold Plated	Ila	41319232-03

RST-L2	Surtext Posts Gold Plated	Ila	41319232-03
RST-L3	Surtext Posts Gold Plated	Ila	41319232-03
RST-L4	Surtext Posts Gold Plated	Ila	41319232-03
RST-L5	Surtext Posts Gold Plated	Ila	41319232-03
RST-L6	Surtext Posts Gold Plated	Ila	41319232-03
RST-EL3	Surtext Posts Gold Plated	Ila	41319232-03
RST-EL4	Surtext Posts Gold Plated	Ila	41319232-03
RST-EL5	Surtext Posts Gold Plated	Ila	41319232-03
RST-EL6	Surtext Posts Gold Plated	Ila	41319232-03
RST-SL3	Surtext Posts Gold Plated	Ila	41319232-03
RST-SL4	Surtext Posts Gold Plated	Ila	41319232-03
RST-SL5	Surtext Posts Gold Plated	Ila	41319232-03

RST-SL6	Surtext Posts Gold Plated	Ila	41319232-03
TST-18	Surtext Posts Titanium intro kit	Ila	41319232-03
TST-60	Surtext Post Titanium starter refill-reamers	Ila	41319232-03
TST-B	Surtext Post Titanium complete starter kit - reamers	Ila	41319232-03
TST	Surtext Posts Titanium assortment – no reamers	Ila	41319232-03
TST-S1	Surtext Posts, Titanium	Ila	41319232-03
TST-S2	Surtext Posts, Titanium	Ila	41319232-03
TST-S3	Surtext Posts, Titanium	Ila	41319232-03
TST-S4	Surtext Posts, Titanium	Ila	41319232-03
TST-S5	Surtext Posts, Titanium	Ila	41319232-03
TST-S6	Surtext Posts, Titanium	Ila	41319232-03
TST-M1	Surtext Posts, Titanium	Ila	41319232-03

TST-M2	Surtext Posts, Titanium	Ila	41319232-03
TST-M3	Surtext Posts, Titanium	Ila	41319232-03
TST-M4	Surtext Posts, Titanium	Ila	41319232-03
TST-M5	Surtext Posts, Titanium	Ila	41319232-03
TST-M6	Surtext Posts, Titanium	Ila	41319232-03
TST-L1	Surtext Posts, Titanium	Ila	41319232-03
TST-L2	Surtext Posts, Titanium	Ila	41319232-03
TST-L3	Surtext Posts, Titanium	Ila	41319232-03
TST-L4	Surtext Posts, Titanium	Ila	41319232-03
TST-L5	Surtext Posts, Titanium	Ila	41319232-03
TST-L6	Surtext Posts, Titanium	Ila	41319232-03
TST-EL3	Surtext Posts, Titanium	Ila	41319232-03
TST-EL4	Surtext Posts, Titanium	Ila	41319232-03
TST-EL5	Surtext Posts, Titanium	Ila	41319232-03
TST-EL6	Surtext Posts, Titanium	Ila	41319232-03
TST-SL3	Surtext Posts, Titanium	Ila	41319232-03

TST-SL4	Surtex Posts, Titanium	Ila	41319232-03
TST-SL5	Surtex Posts, Titanium	Ila	41319232-03
TST-SL6	Surtex Posts, Titanium	Ila	41319232-03
LUC-L5	Luscent Anchor	Ila	41319232-03
LUC-L15	Luscent Anchor	Ila	41319232-03
LUC-M5	Luscent Anchor	Ila	41319232-03
LUC-M15	Luscent Anchor	Ila	41319232-03
LUC-S5	Luscent Anchor	Ila	41319232-03
LUC-S15	Luscent Anchor	Ila	41319232-03
LUC-XS5	Luscent Anchor	Ila	41319232-03
LUC-XS15	Luscent Anchor	Ila	41319232-03
LUC-XXS5	Luscent Anchor	Ila	41319232-03
LUC-XXS15	Luscent Anchor	Ila	41319232-03
LUC-XXXS5	Luscent Anchor	Ila	41319232-03
LUC-XXXS15	Luscent Anchor	Ila	41319232-03
LUC-K3	Luscent Anchor, Starter Kit3	Ila	41319232-03
LUT-L5	Twin Anchor Luscent	Ila	41319232-03
LUT-L15	Twin Anchor Luscent	Ila	41319232-03
LUT-M5	Twin Anchor Luscent	Ila	41319232-03
LUT-M15	Twin Anchor Luscent	Ila	41319232-03
LUT-S5	Twin Anchor Luscent	Ila	41319232-03
LUT-S15	Twin Anchor Luscent	Ila	41319232-03
LUT-XS5	Twin Anchor Luscent	Ila	41319232-03
LUT-XS15	Twin Anchor Luscent	Ila	41319232-03
LUT-K1	Twin Anchor Luscent	Ila	41319232-03
RUA-1/6	Standard Classic Reamers	Ila	41319232-03
RUA-1/3FP,	Standard Classic Reamers	Ila	41319232-03
RUA-2/3FP,	Standard Classic Reamers	Ila	41319232-03
RUA-3/3FP,	Standard Classic Reamers	Ila	41319232-03
RUA-4/3FP,	Standard Classic Reamers	Ila	41319232-03
RUA-5/3FP,	Standard Classic Reamers	Ila	41319232-03
RUA-6/3FP.	Standard Classic Reamers	Ila	41319232-03
RUB-1/6	Standard Classic Reamers	Ila	41319232-03
RUB-1/3FP,	Standard Classic Reamers	Ila	41319232-03

RUB-2/3FP,	Standard Classic Reamers	Ila	41319232-03
RUB-3/3FP,	Standard Classic Reamers	Ila	41319232-03
RUB-4/3FP,	Standard Classic Reamers	Ila	41319232-03
RUB-5/3FP,	Standard Classic Reamers	Ila	41319232-03
RUB-6/3FP.	Standard Classic Reamers	Ila	41319232-03
RUG-1/2,	Standard Conical Reamers	Ila	41319232-03
RUG-2/2,	Standard Conical Reamers	Ila	41319232-03
RUG-3/2,	Standard Conical Reamers	Ila	41319232-03
RUG-4/2,	Standard Conical Reamers	Ila	41319232-03
RUG-5/2,	Standard Conical Reamers	Ila	41319232-03
RUG-6/2	Standard Conical Reamers	Ila	41319232-03
RUH-4/2,	Standard Conical Reamers	Ila	41319232-03
RUH-5/2,	Standard Conical Reamers	Ila	41319232-03
RUH-6/2.	Standard Conical Reamers	Ila	41319232-03
RSA-123,	Helix Classic Reamers	Ila	41319232-03
RSA-345,	Helix Classic Reamers	Ila	41319232-03
RSA-456.	Helix Classic Reamers	Ila	41319232-03
RSA-1/3,	Helix Classic Reamers	Ila	41319232-03
RSA-2/3,	Helix Classic Reamers	Ila	41319232-03
RSA-3/3,	Helix Classic Reamers	Ila	41319232-03
RSA-4/3,	Helix Classic Reamers	Ila	41319232-03
RSA-5/3,	Helix Classic Reamers	Ila	41319232-03
RSA-6/3.	Helix Classic Reamers	Ila	41319232-03
RSB-123,	Helix Classic Reamers	Ila	41319232-03
RSB-345,	Helix Classic Reamers	Ila	41319232-03
RSB-456.	Helix Classic Reamers	Ila	41319232-03
RSB-1/3,	Helix Classic Reamers	Ila	41319232-03
RSB-2/3,	Helix Classic Reamers	Ila	41319232-03
RSB-3/3,	Helix Classic Reamers	Ila	41319232-03
RSB-4/3,	Helix Classic Reamers	Ila	41319232-03
RSB-5/3,	Helix Classic Reamers	Ila	41319232-03
RSB-6/3.	Helix Classic Reamers	Ila	41319232-03
RSC-123,	Helix Classic Reamers	Ila	41319232-03
RSC-345.	Helix Classic Reamers	Ila	41319232-03
RSC-1/2,	Helix Classic Reamers	Ila	41319232-03
RSC-2/2,	Helix Classic Reamers	Ila	41319232-03
RSC-3/2,	Helix Classic Reamers	Ila	41319232-03
RSC-4/2,	Helix Classic Reamers	Ila	41319232-03
RSC-5/2.	Helix Classic Reamers	Ila	41319232-03
RSG-3/3,	Helix Conical Reamers	Ila	41319232-03
RSG-4/3,	Helix Conical Reamers	Ila	41319232-03

RSG-5/3,	Helix Conical Reamers	Ila	41319232-03
RSG-6/3.	Helix Conical Reamers	Ila	41319232-03
RSG-345,	Helix Conical Reamers	Ila	41319232-03
RSG-456.	Helix Conical Reamers	Ila	41319232-03
RSH-3/3,	Helix Conical Reamers	Ila	41319232-03
RSH-4/3,	Helix Conical Reamers	Ila	41319232-03
RSH-5/3,	Helix Conical Reamers	Ila	41319232-03
RSH-6/3.	Helix Conical Reamers	Ila	41319232-03
RSH-345,	Helix Conical Reamers	Ila	41319232-03
RSH-456.	Helix Conical Reamers	Ila	41319232-03
RSI-3/2,	Helix Conical Reamers	Ila	41319232-03
RSI-4/2,	Helix Conical Reamers	Ila	41319232-03
RSI-5/2.	Helix Conical Reamers	Ila	41319232-03
RSI-345.	Helix Conical Reamers	Ila	41319232-03
RUF-1/6	Probos I	Ila	41319232-03
RUD	Probos II	Ila	41319232-03
PDX	Profin PDX	Ila	41319232-03
PDX/SK	Profin PDX	Ila	41319232-03
PDX/CCK	Profin PDX	Ila	41319232-03
PXD-P/SK2	Profin PDX	Ila	41319232-03
LTA/U	Starter Kit; Lamineer Tips with Stand	Ila	41319232-03
LTA	Starter Kit; Lamineer Tips with Stand	Ila	41319232-03
LTA/S	Starter Kit; Lamineer Tips with Stand	Ila	41319232-03
LTA/K1	Overhang Removal Kit	Ila	41319232-03
LTA/K2	Embrasure Shaping Kit	Ila	41319232-03
LTA-150/2	Diamond Red	Ila	41319232-03
LTA-100/2	Diamond Green	Ila	41319232-03
LTA-75/2	Diamond Gold	Ila	41319232-03
LTA-50/2	Diamond Yellow	Ila	41319232-03

LTA-30/2	Diamond White	Ila	41319232-03
LTA-15/2	Diamond Violet	Ila	41319232-03
LTA-39/2	Wolfram Tungsten	Ila	41319232-03
LTA-S150/2	Diamond Red	Ila	41319232-03
LTA-S100/2	Diamond Green	Ila	41319232-03
LTA-S75/2	Diamond Gold	Ila	41319232-03
LTA-S50/2	Diamond Yellow	Ila	41319232-03
LTA-S30/2	Diamond White	Ila	41319232-03
LTA-S15/2	Diamond Violet	Ila	41319232-03
LTA-S36/2	Wolfram Tungsten	Ila	41319232-03
LTA-D150/2	Diamond Red	Ila	41319232-03
LTA-D100/2	Diamond Green	Ila	41319232-03
LTA-D50/2	Diamond Yellow	Ila	41319232-03
LTA-D30/2	Diamond White	Ila	41319232-03
LTA-T50/2	Diamond Yellow	Ila	41319232-03
LTA-T30/2	Diamond White	Ila	41319232-03
LTA-E50/2	50 Micron, yellow	Ila	41319232-03
LTA-C50/2	50 Micron, yellow	Ila	41319232-03
EVA-2000/100	EVA Polishing Tips; Wedge shape, for cleaning of all approximal areas, green	Ila	41319232-03
EVA-5000/100	EVA Polishing Tips; Thin spatula, blue	Ila	41319232-03
LTA-F	Lamineer Tips, Flexible Diamond, Assorted Package, 3 pcs/pkg	Ila	41319232-03
LTA-F100/2	Diamond, Refills, 2 pcs/pkg	Ila	41319232-03
LTA-F75/2	Diamond, Refills, 2 pcs/pkg	Ila	41319232-03

LTA-F50/2	Diamond, Refills, 2 pcs/pkg	Ila	41319232-03
LTA-P/SK2	Lamineer Tips IPR, Stand with Tips	Ila	41319232-03
LTA-P1/2	Black 2 pcs/pkg	Ila	41319232-03
LTA-P2/2	White 2 pcs/pkg	Ila	41319232-03
LTA-P3/2	Yellow 2 pcs/pkg	Ila	41319232-03
LTA-P4/3	Green, 2 pcs/pkg	Ila	41319232-03
LTA-P5/3	Red, 2 pcs/pkg	Ila	41319232-03
LTA-P25R/2	Violet, 2 pcs/pkg	Ila	41319232-03
LTA-P25L/2	Violet, 2 pcs/pkg	Ila	41319232-03

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

Ref Number/ Device Identification	Device Name	Device classification	MDD Certificate Reference(s)
N/A			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
N/A		