

EC CERTIFICATION

EU Quality Management System Certificate

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Dentatus AB

Finspångsgatan 42, SE- 163 53 Spånga, Sweden

Manufacturer SRN: SE-MF-000021392

Scope:

- Dental implants and materials
- Dental instruments
- Active dental instruments, for moist heat sterilization

Certificate Number:

28620156927

Revision:

02

Initial Certification Date:

18 September 2023

Certificate Decision Date:

03 March 2025

Certificate Issue Date:

03 March 2025

Certificate Expiry Date:

27 February 2028



Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.



PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	TD00287-03 Dentatus AB Starter Kit; Lamineer Tips with Stand
	TD00287-02 Profin PDX
	TD00287-001 Luscent Anchor
Audit Report Reference	Stage 1 audit ACTY-2023-622520
	Stage 2 audit ACTY-2023-622521
	Surveillance audit ACTY-2019-383389
	Surveillance audit ACTY-2023-622522

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620156927	18 Sep 2023	Initial certificate
28620156927-01	14 Feb 2024	Extension to scope
28620156927-02	03 Mar 2025	Extension to scope

Certificate Number:
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PRODUCT LIST FOR CERTIFICATE

Issued to: Dentatus AB
Certificate number: 28620156927-02
Certificate valid from: 2025-03-03

Product List Issue Date:
03 March 2025

Product	Classification and EMDN	Intended use ¹	Date Added
Dental implants and materials			
<i>Basic UDI-DI: 735008149ET-190Y4</i>			
ET-190 - Elypse Ti Platforms - 3.5 3.5mm	Class IIa Q01010199		2024-08-14
<i>Basic UDI-DI: 735008149ET-192Y8</i>			
ET-192 - Elypse Ti Platforms - 4.0 4.0mm	Class IIa Q01010199		2024-08-14
<i>Basic UDI-DI: 735008149LUCJL</i>			
LUC-L15 - Luscent Anchor	Class IIa Q01010199		2023-09-18
LUC-L5 - Luscent Anchor	Class IIa Q01010199		2023-09-18
LUC-M15 - Luscent Anchor	Class IIa Q01010199		2023-09-18
LUC-M5 - Luscent Anchor	Class IIa Q01010199		2023-09-18
LUC-S15 - Luscent Anchor	Class IIa Q01010199		2023-09-18
LUC-S5 - Luscent Anchor	Class IIa Q01010199		2023-09-18
LUC-XS15 - Luscent Anchor	Class IIa Q01010199		2023-09-18
LUC-XS5 - Luscent Anchor	Class IIa Q01010199		2023-09-18
LUC-XXS15 - Luscent Anchor	Class IIa Q01010199		2023-09-18
LUC-XXS5 - Luscent Anchor	Class IIa Q01010199		2023-09-18
LUC-XXXS15 - Luscent Anchor	Class IIa Q01010199		2023-09-18
LUC-XXXS5 - Luscent Anchor	Class IIa Q01010199		2023-09-18
<i>Basic UDI-DI: 735008149LUC-K395</i>			

¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.



Product	Classification and EMDN	Intended use ¹	Date Added
LUC-K3 - Luscent Anchor, Starter Kit3	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149LUT-K1CQ			
LUT-K1 - Twin Luscent, Starter Kit 1	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149LUTKN			
LUT-L15 - Twin Anchor Luscent	Class IIa Q01010199		2023-09-18
LUT-L5 - Twin Anchor Luscent	Class IIa Q01010199		2023-09-18
LUT-M15 - Twin Anchor Luscent	Class IIa Q01010199		2023-09-18
LUT-M5 - Twin Anchor Luscent	Class IIa Q01010199		2023-09-18
LUT-S15 - Twin Anchor Luscent	Class IIa Q01010199		2023-09-18
LUT-S5 - Twin Anchor Luscent	Class IIa Q01010199		2023-09-18
LUT-XS15 - Twin Anchor Luscent	Class IIa Q01010199		2023-09-18
LUT-XS5 - Twin Anchor Luscent	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149PGp-P240X6			
PG-240 - Starter Kit, no reamers;1 hollow key, 1 cross key, 20 stoppers <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149PGp-P60P6			
PG-60 - Starter Kit, no reamers; 1 hollow key, 1 cross key, 20 stoppers <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149PGp-PDZ			
PG-EL3 - Refills 12 psc/pkg, Extra Long 14.2 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-EL4 - Refills 12 psc/pkg, Extra Long 14.2 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-EL5 - Refills 12 psc/pkg, Extra Long 14.2 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-EL6 - Refills 12 psc/pkg, Extra Long 14.2 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18

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Certificate number: 28620156927-02

Product list issue date: 03 March 2025



Product	Classification and EMDN	Intended use ¹	Date Added
PG-L1 - Refills 12 psc/pkg, Long 11.8 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-L2 - Refills 12 psc/pkg, Long 11.8 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-L3 - Refills 12 psc/pkg, Long 11.8 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-L4 - Refills 12 psc/pkg, Long 11.8 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-L5 - Refills 12 psc/pkg, Long 11.8 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-L6 - Refills 12 psc/pkg, Long 11.8 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-M1 - Refills 12 psc/pkg, Medium 9.3 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-M2 - Refills 12 psc/pkg, Medium 9.3 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-M3 - Refills 12 psc/pkg, Medium 9.3 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-M4 - Refills 12 psc/pkg, Medium 9.3 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-M5 - Refills 12 psc/pkg, Medium 9.3 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-M6 - Refills 12 psc/pkg, Medium 9.3 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-S1 - Refills 12 psc/pkg, Short 7.8 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-S2 - Refills 12 psc/pkg, Short 7.8 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-S3 - Refills 12 psc/pkg, Short 7.8 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-S4 - Refills 12 psc/pkg, Short 7.8 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18

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Product	Classification and EMDN	Intended use ¹	Date Added
PG-S5 - Refills 12 psc/pkg, Short 7.8 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
PG-S6 - Refills 12 psc/pkg, Short 7.8 mm <i>Parmax Classic Posts, Gold Plated</i>	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149PTi-P60S2			
PT-60 - Starter Kit, 60 Anchors <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149PTi-PFR			
PT-EL-3, - Refills 12 psc/pkg, Extra Long 14.2 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-EL4, - Refills 12 psc/pkg, Extra Long 14.2 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-EL5, - Refills 12 psc/pkg, Extra Long 14.2 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-EL6, - Refills 12 psc/pkg, Extra Long 14.2 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-L1, - Refills 12 psc/pkg, Long 11.8 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-L2, - Refills 12 psc/pkg, Long 11.8 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-L3, - Refills 12 psc/pkg, Long 11.8 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-L4, - Refills 12 psc/pkg, Long 11.8 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-L5, - Refills 12 psc/pkg, Long 11.8 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-L6, - Refills 12 psc/pkg, Long 11.8 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-M1, - Refills 12 psc/pkg, Medium 9.3 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-M2, - Refills 12 psc/pkg, Medium 9.3 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18

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Product list issue date: 03 March 2025



Product	Classification and EMDN	Intended use ¹	Date Added
PT-M3, - Refills 12 psc/pkg, Medium 9.3 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-M4, - Refills 12 psc/pkg, Medium 9.3 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-M5, - Refills 12 psc/pkg, Medium 9.3 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-M6, - Refills 12 psc/pkg, Medium 9.3 mm <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-S1, - Refills 12 pcs/pkg, Short 7.8 mm; <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-S2, - Refills 12 pcs/pkg, Short 7.8 mm; <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-S3, - Refills 12 pcs/pkg, Short 7.8 mm; <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-S4, - Refills 12 pcs/pkg, Short 7.8 mm; <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-S5, - Refills 12 pcs/pkg, Short 7.8 mm; <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
PT-S6, - Refills 12 pcs/pkg, Short 7.8 mm; <i>Parmax Classic Posts, Titanium</i>	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149RST-18CK			
RST-18 - Surtex Posts Gold Plated intro kit	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149RST-60CJ			
RST-60 - Surtex Post Gold Plated assortment	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149RST-BCU			
RST-B - Surtex Post Gold Plated complete starter kit - reamers	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149RSTLE			
RST - Surtex Posts Gold Plated assortment – no reamers	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149RST-XE8			

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Certificate number: 28620156927-02

Product list issue date: 03 March 2025



Product	Classification and EMDN	Intended use ¹	Date Added
RST-EL3 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-EL4 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-EL5 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-EL6 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-L1 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-L2 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-L3 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-L4 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-L5 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-L6 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-M1 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-M2 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-M3 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-M4 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-M5 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-M6 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-S1 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-S2 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-S3 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-S4 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-S5 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-S6 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-SL3 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18

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Certificate number: 28620156927-02
 Product list issue date: 03 March 2025



Product	Classification and EMDN	Intended use ¹	Date Added
RST-SL4 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-SL5 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
RST-SL6 - Surtex Posts Gold Plated	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149SR-111-285			
SR-111-2 - Ti Platforms for Interim Crowns	Class IIa Q01010199		2024-08-14
Basic UDI-DI: 735008149SR-45-24Z			
SR-45-2 - Ti Screwcaps	Class IIa Q01010199		2024-08-14
Basic UDI-DI: 735008149SR-4977			
SR-49 - Ti Index Platforms for Interim Multi-Unit Restorations	Class IIa Q01010199		2024-08-14
Basic UDI-DI: 735008149SR-61-24T			
SR-61-2 - Ti Connective Bars	Class IIa Q01010199		2024-08-14
Basic UDI-DI: 735008149SR-62-24Y			
SR-62-2 - Resin Screwcaps - White	Class IIa Q01010199		2024-08-14
Basic UDI-DI: 735008149SR-97-26E			
SR-97-2 - Resin Platforms for Temporary Crowns	Class IIa Q01010199		2024-08-14
Basic UDI-DI: 735008149SST-18CY			
SST-18 - Surtex Posts/Stainless steel intro kit	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149SST-60CX			
SST-60 - Surtex Post /Stainless steel starter refill-reamers	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149SST-BD7			
SST-B - Surtex Post / Stainless steel complete starter kit - reamers	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149SSTLK			
SST - Surtex Posts /Stainless steel assortment – no reamers	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149SST-XEK			

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Certificate number: 28620156927-02

Product list issue date: 03 March 2025



Product	Classification and EMDN	Intended use ¹	Date Added
SST-EL3 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-EL4 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-EL5 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-EL6 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-L1 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-L2 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-L3 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-L4 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-L5 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-L6 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-M1 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-M2 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-M3 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-M4 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-M5 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-M6 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-S1 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-S2 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-S3 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-S4 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-S5 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-S6 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-SL3 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18

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Certificate number: 28620156927-02
 Product list issue date: 03 March 2025



Product	Classification and EMDN	Intended use ¹	Date Added
SST-SL4 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-SL5 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-SL6 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149TST-18DD			
TST-18 - Surtex Posts Titanium intro kit	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149TST-60DC			
TST-60 - Surtex Post Titanium starter refill-reamers	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149TST-BDJ			
TST-B - Surtex Post Titanium complete starter kit - reamers	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149TSTLQ			
TST - Surtex Posts Titanium assortment – no reamers	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149TST-XEW			
TST-EL3 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-EL4 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-EL5 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-EL6 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-L1 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-L2 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-L3 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-L4 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-L5 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-L6 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-M1 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-M2 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18

¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use ¹	Date Added
TST-M3 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-M4 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-M5 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-M6 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-S1 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-S2 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-S3 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-S4 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-S5 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-S6 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-SL3 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-SL4 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-SL5 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
TST-SL6 - Surtex Posts, Titanium	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735011489PPI-PF5			
PL L15 - Paralight 15 posts, with marking cap	Class IIa Q01010199		2023-09-18
PL M15 - Paralight 15 posts, with marking cap	Class IIa Q01010199		2023-09-18
PL S15 - Paralight 15 posts, with marking cap	Class IIa Q01010199		2023-09-18
PL XS15 - Paralight 15 posts, with marking cap	Class IIa Q01010199		2023-09-18
Dental instruments			
Basic UDI-DI: 735008149AR-110V2			
AR-110 - R/A Hpc. Driver	Class IIa Q01010199		2024-08-14
Basic UDI-DI: 735008149CePo-SYS1ZG			

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Certificate number: 28620156927-02
 Product list issue date: 03 March 2025



Product	Classification and EMDN	Intended use ¹	Date Added
MR-1041 - Center Point (CePo) Drills - System 1 1.8mm L	Class IIa Q01010199		2024-08-14
MR-1042 - Center Point (CePo) Drills - System 1 1.8mm S	Class IIa Q01010199		2024-08-14
MR-1045 - Center Point (CePo) Drills - System 1 2.2mm	Class IIa Q01010199		2024-08-14
MR-1046 - Center Point (CePo) Drills - System 1 2.4mm	Class IIa Q01010199		2024-08-14
MR-1047 - Center Point (CePo) Drills - System 1 2.8mm	Class IIa Q01010199		2024-08-14
Basic UDI-DI: 735008149CePo-SYS2ZJ			
MR-1141 - Center Point (CePo) Drills - System 2 1.8mm L	Class IIa Q01010199		2024-08-14
MR-1142 - Center Point (CePo) Drills - System 2 1.8mm S	Class IIa Q01010199		2024-08-14
MR-1145 - Center Point (CePo) Drills - System 2 2.2mm	Class IIa Q01010199		2024-08-14
MR-1146 - Center Point (CePo) Drills - System 2 2.4mm	Class IIa Q01010199		2024-08-14
MR-1147 - Center Point (CePo) Drills - System 2 2.8mm	Class IIa Q01010199		2024-08-14
Basic UDI-DI: 735008149EVAHG			
EVA-2000/100 - EVA Polishing Tips; Wedge shape, for cleaning of all approximal areas, green	Class IIa Q010199		2024-02-14
EVA-5000/100 - EVA Polishing Tips; Thin spatula, blue	Class IIa Q010199		2024-02-14
Basic UDI-DI: 735008149HCUJ			
RSA-1/3, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSA-123, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSA-2/3, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSA-3/3, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14

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Certificate number: 28620156927-02
 Product list issue date: 03 March 2025



Product	Classification and EMDN	Intended use ¹	Date Added
RSA-345, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSA-4/3, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSA-456, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSA-5/3, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSA-6/3, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSB-1/3, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSB-123, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSB-2/3, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSB-3/3, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSB-345, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSB-4/3, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSB-456, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSB-5/3, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSB-6/3, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSC-1/2, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSC-123, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSC-2/2, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSC-3/2, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSC-345, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSC-4/2, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
RSC-5/2, - Helix Classic Reamers	Class IIa Q01010199		2024-02-14
Basic UDI-DI: 735008149HCoJQ			
RSG-3/3, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSG-345, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14

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Certificate number: 28620156927-02

Product list issue date: 03 March 2025



Product	Classification and EMDN	Intended use ¹	Date Added
RSG-4/3, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSG-456, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSG-5/3, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSG-6/3, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSH-3/3, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSH-345, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSH-4/3, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSH-456, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSH-5/3, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSH-6/3, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSI-3/2, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSI-345, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSI-4/2, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
RSI-5/2, - Helix Conical Reamers	Class IIa Q01010199		2024-02-14
Basic UDI-DI: 735008149IPRIL			
LTA-P/SK2 - Lamineer Tips IPR, Stand with Tips <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-P1/2 - Black 2 pcs/pkg <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-P2/2 - White 2 pcs/pkg <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-P25L/2 - Violet, 2 pcs/pkg <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-P25R/2 - Violet, 2 pcs/pkg <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-P3/2 - Yellow 2 pcs/pkg <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-P4/3 - Green, 2 pcs/pkg <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-P5/3 - Red, 2 pcs/pkg <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14

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Certificate number: 28620156927-02
Product list issue date: 03 March 2025



Product	Classification and EMDN	Intended use ¹	Date Added
Basic UDI-DI: 735008149LTA-F8A			
LTA-F100/2 - Diamond, Refills, 2 pcs/pkg <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-F50/2 - Diamond, Refills, 2 pcs/pkg <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-F75/2 - Diamond, Refills, 2 pcs/pkg <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-F - Lamineer Tips, Flexible Diamond, Assorted Package, 3 pcs/pkg <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
Basic UDI-DI: 735008149LTAJD			
LTA/K1 - Overhang Removal Kit <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA/K2 - Embrasure Shaping Kit <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA/S - Starter Kit; Lamineer Tips with Stand <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA/U - Starter Kit; Lamineer Tips with Stand <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-100/2 - Diamond Green <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-15/2 - Diamond Violet <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-150/2 - Diamond Red <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-30/2 - Diamond White <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-39/2 - Wolfram Tungsten <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-50/2 - Diamond Yellow <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-75/2 - Diamond Gold <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-C50/2 - 50 Micron, yellow <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-D100/2 - Diamond Green <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-D150/2 - Diamond Red <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-D30/2 - Diamond White <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-D50/2 - Diamond Yellow <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14

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Certificate number: 28620156927-02
Product list issue date: 03 March 2025



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LTA-E50/2 - 50 Micron, yellow <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-S100/2 - Diamond Green <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-S15/2 - Diamond Violet <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-S150/2 - Diamond Red <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-S30/2 - Diamond White <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-S36/2 - Wolfram Tungsten <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-S50/2 - Diamond Yellow <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-S75/2 - Diamond Gold <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA - Starter Kit; Lamineer Tips with Stand <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-T30/2 - Diamond White <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
LTA-T50/2 - Diamond Yellow <i>Lamineer Tips</i>	Class IIa Q010199		2024-02-14
Basic UDI-DI: 735008149PDXJX			
PDX/CCK - Profin PDX	Class IIa Q010199		2025-03-03
PDX/SK - Profin PDX	Class IIa Q010199		2025-03-03
PDX-P/SK2 - Profin PDX	Class IIa Q010199		2025-03-03
PDX - Profin PDX	Class IIa Q010199		2025-03-03
Basic UDI-DI: 735008149RUDKL			
RUD - Probos II	Class IIa Q01010199		2024-02-14
Basic UDI-DI: 735008149RUFKQ			
RUF-1/6 - Probos I	Class IIa Q01010199		2024-02-14
Basic UDI-DI: 735008149SCIL9			
RUA-1/3FP, - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
RUA-1/6 - Standard Classic Reamers	Class IIa Q01010199		2024-02-14

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Certificate number: 28620156927-02
Product list issue date: 03 March 2025



Product	Classification and EMDN	Intended use ¹	Date Added
RUA-2/3FP, - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
RUA-3/3FP, - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
RUA-4/3FP, - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
RUA-5/3FP, - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
RUA-6/3FP, - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
RUB-1/3FP, - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
RUB-1/6 - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
RUB-2/3FP, - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
RUB-3/3FP, - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
RUB-4/3FP, - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
RUB-5/3FP, - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
RUB-6/3FP, - Standard Classic Reamers	Class IIa Q01010199		2024-02-14
Basic UDI-DI: 7350081495CoLF			
RUG-1/2, - Standard Conical Reamers	Class IIa Q01010199		2024-02-14
RUG-2/2, - Standard Conical Reamers	Class IIa Q01010199		2024-02-14
RUG-3/2, - Standard Conical Reamers	Class IIa Q01010199		2024-02-14
RUG-4/2, - Standard Conical Reamers	Class IIa Q01010199		2024-02-14
RUG-5/2, - Standard Conical Reamers	Class IIa Q01010199		2024-02-14
RUG-6/2 - Standard Conical Reamers	Class IIa Q01010199		2024-02-14
RUH-4/2, - Standard Conical Reamers	Class IIa Q01010199		2024-02-14
RUH-5/2, - Standard Conical Reamers	Class IIa Q01010199		2024-02-14
RUH-6/2, - Standard Conical Reamers	Class IIa Q01010199		2024-02-14
Basic UDI-DI: 7350081495SR-57-15G			
SR-57-1 - R/A Hpc. Driver	Class IIa Q01010199		2024-08-14

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Certificate number: 28620156927-02

Product list issue date: 03 March 2025



Product	Classification and EMDN	Intended use ¹	Date Added
Basic UDI-DI: 735011489PCI-RCE			
PRA-1/3FP - Parmax Classic Reamers, Refills, Short (3 pcs/pkg)	Class IIa Q01010199		2024-02-14
PRA-1/6 - Parmax Classic Reamers, Short Assortment	Class IIa Q01010199		2024-02-14
PRA-2/3FP - Parmax Classic Reamers, Refills, Short (3 pcs/pkg)	Class IIa Q01010199		2024-02-14
PRA-3/3FP - Parmax Classic Reamers, Refills, Short (3 pcs/pkg)	Class IIa Q01010199		2024-02-14
PRA-4/3FP - Parmax Classic Reamers, Refills, Short (3 pcs/pkg)	Class IIa Q01010199		2024-02-14
PRA-5/3FP - Parmax Classic Reamers, Refills, Short (3 pcs/pkg)	Class IIa Q01010199		2024-02-14
PRA-6/3FP - Parmax Classic Reamers, Refills, Short (3 pcs/pkg)	Class IIa Q01010199		2024-02-14
PRB-1/3FP, - Parmax Classic Reamers, Refills, Long (3 pcs/pkg)	Class IIa Q01010199		2024-02-14
PRB-1/6 - Parmax Classic Reamers, Long Assortment	Class IIa Q01010199		2024-02-14
PRB-2/3FP, - Parmax Classic Reamers, Refills, Long (3 pcs/pkg)	Class IIa Q01010199		2024-02-14
PRB-3/3FP - Parmax Classic Reamers, Refills, Long (3 pcs/pkg)	Class IIa Q01010199		2024-02-14
PRB-4/3FP - Parmax Classic Reamers, Refills, Long (3 pcs/pkg)	Class IIa Q01010199		2024-02-14
PRB-5/3FP - Parmax Classic Reamers, Refills, Long (3 pcs/pkg)	Class IIa Q01010199		2024-02-14
PRB-6/3F - Parmax Classic Reamers, Refills, Long (3 pcs/pkg)	Class IIa Q01010199		2024-02-14
Basic UDI-DI: 735011489PPI-RF9			
PLR-3/2 - Parmax Paralight Reamers (2 pcs/pkg)	Class IIa Q01010199		2024-02-14
PLR-4/2 - Parmax Paralight Reamers (2 pcs/pkg)	Class IIa Q01010199		2024-02-14
PLR-5/2 - Parmax Paralight Reamers (2 pcs/pkg)	Class IIa Q01010199		2024-02-14
PLR-6/2 - Parmax Paralight Reamers (2 pcs/pkg)	Class IIa Q01010199		2024-02-14

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Certificate number: 28620156927-02

Product list issue date: 03 March 2025



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Brian Mather

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Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

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Certificate number: 28620156927-02
Product list issue date: 03 March 2025

