

EC CERTIFICATION

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

Certificate Number:

28620156927

Revision:

00

Initial Certification Date:

18 September 2023

Certificate Decision Date:

18 September 2023

Certificate Issue Date:

18 September 2023

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	TD00287-01 Dentatus AB Luscent Anchor
Audit Report Reference	Stage 1 audit ACTY-2023-622520
	Stage 2 audit ACTY-2023-622521

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620156927

Revision:
00

Initial Certification Date:
18 September 2023

Certificate Decision Date:
18 September 2023

Certificate Issue Date:
18 September 2023

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.



Certificate No: 28620156927
 Date: 18 September 2023
 Handled by: Caroline Åman
 E-mail: IMNB@intertek.com

Dentatus AB
 Attn: Maggie Holland
 Finspångsgatan 42
 SE- 163 53 Spånga
 Sweden

Purpose

Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.
 Expiry date on MDR certificate is set to be aligned with client’s audit cycle for ISO 13485:2016 certificate.

Activity

Audit Type	Location	Auditor Name	Audit Date
Stage 1 ACTY-2023-622520	Spånga,	Gabriel Johansson	4 – 5 May 2023
Stage 2 ACTY-2023-622521	Spånga,	Gabriel Johansson	27 – 29 June 2023

Technical Documentation Report	Assessor Name	Assessment Date
MDR TD Assessment Report_Dentatus_Luscent Anchor_TD00287-01-R2_2023-05-25.signed	Lian Zhang	25 May 2023
MDR CEAR.Dentatus_Luscent Anchor_TD00287-01_2023-05-25.signed	Lian Zhang	25 May 2023
MDR SSCP Checklist_Dentatus_Luscent Anchor_TD00287-01_2023-05-16.LZG signed	Lian Zhang	16 May 2023
MDR TD Request for Additional Information_Dentatus_TD00287-01_2023-05-16.draft	Lian Zhang	1 May 2023
MDR Pre-Assessment Non-Conformities_Dentatus Luscent Anchor_TD00287-01_2023-02-23_TD00287-01	Mark A Brown	23 Feb 2023

Scope of assessment

Dental implants and materials, Class IIa

Result

1 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.

All non-conformities noted during the technical documentation assessment have been closed.

Certificate Valid from

18 September 2023

Conclusions/Decisions

Referring to the above, a Certificate of Conformance with the Medical Device Regulation 2017/745, Annex IX will be issued. The Certificate is valid for products specified in the “MDR – Product List”.

Follow-up assessments

Follow-up assessments are going to be performed once per year.

Appeals


Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Others

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body has the right to review this documentation.

Intertek Medical Notified Body AB
Notified Body MDR

Brian Mather
Certification Authority (TD Assessment)



Mikael Hagelin
Certification Authority (Audit)

PRODUCT LIST FOR CERTIFICATE

Issued to: Dentatus AB
Certificate number: 28620156927
Certificate valid from: 2023-09-18

Product List Issue Date:
18 September 2023

Product	Classification and EMDN	Intended use ¹	Date Added
Dental implants and materials			
<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>			
LUC-K3 - Luscent Anchor, Starter Kit3	Class IIa Q01010199		2023-09-18
<i>Basic UDI-DI: 735008149LUT-K1CQ</i>			
LUT-K1 - Twin Anchor Luscent	Class IIa Q01010199		2023-09-18
<i>Basic UDI-DI: 735008149LUTKN</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
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
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

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

Certificate number: 28620156927

Product list issue date: 18 September 2023



Product	Classification and EMDN	Intended use ¹	Date Added
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
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

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

Certificate number: 28620156927

Product list issue date: 18 September 2023



Product	Classification and EMDN	Intended use ¹	Date Added
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
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

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

Certificate number: 28620156927

Product list issue date: 18 September 2023



Product	Classification and EMDN	Intended use ¹	Date Added
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			
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

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

Certificate number: 28620156927

Product list issue date: 18 September 2023



Product	Classification and EMDN	Intended use ¹	Date Added
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
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: 735008149SST-18CY			
SST-18 - Surtex Posts/Stainless steel intro kit	Class IIa Q01010199		2023-09-18
Basic UDI-DI: 735008149SST-60CX			

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

Certificate number: 28620156927

Product list issue date: 18 September 2023



Product	Classification and EMDN	Intended use ¹	Date Added
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			
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

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

Certificate number: 28620156927

Product list issue date: 18 September 2023



Product	Classification and EMDN	Intended use ¹	Date Added
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
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

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

Certificate number: 28620156927

Product list issue date: 18 September 2023



Product	Classification and EMDN	Intended use ¹	Date Added
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
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

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

Certificate number: 28620156927

Product list issue date: 18 September 2023



Product	Classification and EMDN	Intended use ¹	Date Added
---------	-------------------------	---------------------------	------------



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.

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

Certificate number: 28620156927

Product list issue date: 18 September 2023

