

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 Number:

28620156927

Revision:

00

Initial Certification Date:

18 September 2023

Certificate Decision Date:

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Certificate Issue Date:

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27 February 2028

CERTIFICATE HISTORY

PRECEDING CERTIFICATE	DATE OF ISSUE	IDENTIFICATION OF CHANGES
NUMBER		

Brian Mather Certification Authority, MDR Intertek Medical Notified Body AB, Torshamnsgatan 43,

Box 1103, SE-164 22 Kista, Sweden

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MDR – Decision Report

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	Spånga,	Gabriel	4 – 5 May
ACTY-2023-622520		Johansson	2023
Stage 2	Spånga,	Gabriel	27 – 29 June
ACTY-2023-622521		Johansson	2023

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

Scope of assessment Den

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.



MDR – Decision Report

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)

Hikash Day Qi

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			
Basic UDI-DI: 735008149LUCJL			
LUC-L15 - Luscent Anchor	Class IIa		2023-09-18
	Q01010199		
LUC-L5 - Luscent Anchor	Class IIa		2023-09-18
	Q01010199		
LUC-M15 - Luscent Anchor	Class IIa		2023-09-18
	Q01010199		
LUC-M5 - Luscent Anchor	Class IIa		2023-09-18
	Q01010199		
LUC-S15 - Luscent Anchor	Class IIa		2023-09-18
	Q01010199		
LUC-S5 - Luscent Anchor	Class IIa		2023-09-18
	Q01010199		
LUC-XS15 - Luscent Anchor	Class IIa		2023-09-18
	Q01010199		
LUC-XS5 - Luscent Anchor	Class IIa		2023-09-18
	Q01010199		
LUC-XXS15 - Luscent Anchor	Class IIa		2023-09-18
	Q01010199		
LUC-XXS5 - Luscent Anchor	Class IIa		2023-09-18
	Q01010199		
LUC-XXXS15 - Luscent Anchor	Class IIa		2023-09-18
	Q01010199		
LUC-XXXS5 - Luscent Anchor	Class IIa		2023-09-18
	Q01010199		
Basic UDI-DI: 735008149LUC-K395			
LUC-K3 - Luscent Anchor, Starter Kit3	Class IIa		2023-09-18
•	Q01010199		
Basic UDI-DI: 735008149LUT-K1CQ			
LUT-K1 - Twin Anchor Luscent	Class IIa		2023-09-18
	Q01010199		









Product	Classification and EMDN	Intended use ¹	Date Added
LUT-L15 - Twin Anchor Luscent	Class IIa		2023-09-18
	Q01010199		
LUT-L5 - Twin Anchor Luscent	Class IIa		2023-09-18
	Q01010199		
LUT-M15 - Twin Anchor Luscent	Class IIa		2023-09-18
	Q01010199		
LUT-M5 - Twin Anchor Luscent	Class IIa		2023-09-18
	Q01010199		
LUT-S15 - Twin Anchor Luscent	Class IIa		2023-09-18
	Q01010199		
LUT-S5 - Twin Anchor Luscent	Class IIa		2023-09-18
	Q01010199		
LUT-XS15 - Twin Anchor Luscent	Class IIa		2023-09-18
	Q01010199		
LUT-XS5 - Twin Anchor Luscent	Class IIa		2023-09-18
	Q01010199		
Basic UDI-DI: 735008149PGp-P240X6			
PG-240 - Starter Kit, no reamers;1	Class IIa		2023-09-18
hollow key, 1 cross key, 20 stoppers	Q01010199		
Parmax Classic Posts, Gold Plated			
Basic UDI-DI: 735008149PGp-P60P6			
PG-60 - Starter Kit, no reamers; 1	Class IIa		2023-09-18
hollow key, 1 cross key, 20 stoppers	Q01010199		
Parmax Classic Posts, Gold Plated			
Basic UDI-DI: 735008149PGp-PDZ			
PG-EL3 - Refills 12 psc/pkg, Extra Long	Class IIa		2023-09-18
14.2 mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-EL4 - Refills 12 psc/pkg, Extra Long	Class IIa		2023-09-18
14.2 mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-EL5 - Refills 12 psc/pkg, Extra Long	Class IIa		2023-09-18
14.2 mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-EL6 - Refills 12 psc/pkg, Extra Long	Class IIa		2023-09-18
14.2 mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-L1 - Refills 12 psc/pkg, Long 11.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-L2 - Refills 12 psc/pkg, Long 11.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-L3 - Refills 12 psc/pkg, Long 11.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Gold Plated			

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
PG-L4 - Refills 12 psc/pkg, Long 11.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-L5 - Refills 12 psc/pkg, Long 11.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-L6 - Refills 12 psc/pkg, Long 11.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-M1 - Refills 12 psc/pkg, Medium	Class IIa		2023-09-18
9.3 mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-M2 - Refills 12 psc/pkg, Medium	Class IIa		2023-09-18
9.3 mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-M3 - Refills 12 psc/pkg, Medium	Class IIa		2023-09-18
9.3 mm	Q01010199		2020 00 10
Parmax Classic Posts, Gold Plated			
PG-M4 - Refills 12 psc/pkg, Medium	Class IIa		2023-09-18
9.3 mm	Q01010199		2023 03 10
Parmax Classic Posts, Gold Plated	2220200		
PG-M5 - Refills 12 psc/pkg, Medium	Class IIa		2023-09-18
9.3 mm	Q01010199		2023-03-18
Parmax Classic Posts, Gold Plated	Q01010133		
PG-M6 - Refills 12 psc/pkg, Medium	Class IIa		2023-09-18
9.3 mm	Q01010199		2023-03-18
Parmax Classic Posts, Gold Plated	Q01010133		
·	Class IIa		2023-09-18
PG-S1 - Refills 12 psc/pkg, Short 7.8			2025-09-18
mm Parmax Classic Posts, Gold Plated	Q01010199		
<u> </u>	Cl II -		2022 00 40
PG-S2 - Refills 12 psc/pkg, Short 7.8	Class IIa		2023-09-18
mm Parmay Classic Posts Gold Plated	Q01010199		
Parmax Classic Posts, Gold Plated	Class II		2022 22 42
PG-S3 - Refills 12 psc/pkg, Short 7.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Gold Plated	Cl:		4442 22 42
PG-S4 - Refills 12 psc/pkg, Short 7.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-S5 - Refills 12 psc/pkg, Short 7.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Gold Plated			
PG-S6 - Refills 12 psc/pkg, Short 7.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Gold Plated			
Basic UDI-DI: 735008149PTi-P60S2			
PT-60 - Starter Kit, 60 Anchors	Class IIa		2023-09-18
Parmax Classic Posts, Titanium	Q01010199		

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
Basic UDI-DI: 735008149PTi-PFR			
PT-EL-3, - Refills 12 psc/pkg, Extra Long	Class IIa		2023-09-18
14.2 mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-EL4, - Refills 12 psc/pkg, Extra Long	Class IIa		2023-09-18
14.2 mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-EL5, - Refills 12 psc/pkg, Extra Long	Class IIa		2023-09-18
14.2 mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-EL6 Refills 12 psc/pkg, Extra Long	Class IIa		2023-09-18
14.2 mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-L1, - Refills 12 psc/pkg, Long 11.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-L2, - Refills 12 psc/pkg, Long 11.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-L3, - Refills 12 psc/pkg, Long 11.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-L4, - Refills 12 psc/pkg, Long 11.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-L5, - Refills 12 psc/pkg, Long 11.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-L6 Refills 12 psc/pkg, Long 11.8	Class IIa		2023-09-18
mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-M1, - Refills 12 psc/pkg, Medium	Class IIa		2023-09-18
9.3 mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-M2, - Refills 12 psc/pkg, Medium	Class IIa		2023-09-18
9.3 mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-M3, - Refills 12 psc/pkg, Medium	Class IIa		2023-09-18
9.3 mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-M4, - Refills 12 psc/pkg, Medium	Class IIa		2023-09-18
9.3 mm	Q01010199		
Parmax Classic Posts, Titanium			
PT-M5, - Refills 12 psc/pkg, Medium	Class IIa		2023-09-18
9.3 mm	Q01010199		
Parmax Classic Posts, Titanium			

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
RST-L2 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-L3 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-L4 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-L5 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-L6 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-M1 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-M2 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-M3 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-M4 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-M5 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-M6 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-S1 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-S2 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-S3 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-S4 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		2020 00 20
RST-S5 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		
RST-S6 - Surtex Posts Gold Plated	Class IIa		2023-09-18
	Q01010199		2020 03 10
RST-SL3 - Surtex Posts Gold Plated	Class IIa		2023-09-18
NOT DEST SUITEN FOSTS GOIG Fluted	Q01010199		2023 03 10
RST-SL4 - Surtex Posts Gold Plated	Class IIa		2023-09-18
JET Janten 1 0313 Gold Hateu	Q01010199		2023-03-10
RST-SL5 - Surtex Posts Gold Plated	Class IIa		2023-09-18
NOT SES - SuiteA i Osts Goid Fidted	Q01010199		2023-03-18
RST-SL6 - Surtex Posts Gold Plated	Class IIa		2023-09-18
NOT SEO - Sui lex Posts Goid Fidied	Q01010199		2023-03-18
Basic UDI-DI: 735008149SST-18CY	Q01010199		
SST-18 - Surtex Posts/Stainless steel	Class IIa	-	2023-09-18
intro kit	Q01010199		

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	Class IIa		2023-09-18
starter refill-reamers	Q01010199		
Basic UDI-DI: 735008149SST-BD7			
SST-B - Surtex Post / Stainless steel	Class IIa		2023-09-18
complete starter kit - reamers	Q01010199		
Basic UDI-DI: 735008149SSTLK			
SST - Surtex Posts /Stainless steel	Class IIa		2023-09-18
assortment – no reamers	Q01010199		
Basic UDI-DI: 735008149SST-XEK			
SST-EL3 - Surtex Post Stainless Steel	Class IIa		2023-09-18
	Q01010199		
SST-EL4 - Surtex Post Stainless Steel	Class IIa		2023-09-18
	Q01010199		
SST-EL5 - Surtex Post Stainless Steel	Class IIa Q01010199		2023-09-18
SST-EL6 - Surtex Post Stainless Steel	Class IIa		2023-09-18
	Q01010199		
SST-L1 - Surtex Post Stainless Steel	Class IIa		2023-09-18
	Q01010199		
SST-L2 - Surtex Post Stainless Steel	Class IIa		2023-09-18
	Q01010199		
SST-L3 - Surtex Post Stainless Steel	Class IIa		2023-09-18
	Q01010199		
SST-L4 - Surtex Post Stainless Steel	Class IIa		2023-09-18
	Q01010199		
SST-L5 - Surtex Post Stainless Steel	Class IIa		2023-09-18
	Q01010199		
SST-L6 - Surtex Post Stainless Steel	Class IIa		2023-09-18
	Q01010199		
SST-M1 - Surtex Post Stainless Steel	Class IIa		2023-09-18
	Q01010199		
SST-M2 - Surtex Post Stainless Steel	Class IIa		2023-09-18
	Q01010199		
SST-M3 - Surtex Post Stainless Steel	Class IIa		2023-09-18
	Q01010199		2022.00.40
SST-M4 - Surtex Post Stainless Steel	Class IIa		2023-09-18
CCT ME Current Door Chaimless Charle	Q01010199		2022 00 40
SST-M5 - Surtex Post Stainless Steel	Class IIa		2023-09-18
SST-M6 - Surtex Post Stainless Steel	Q01010199 Class IIa		2022 00 10
331-IVIO - 301 LEX FOST STAITHESS STEEL	Q01010199		2023-09-18
SST-S1 - Surtex Post Stainless Steel	Class IIa		2023-09-18
221-21 - 201 fex Lost 2fq111622 2f661	Q01010199		2023-03-18
SST-S2 - Surtex Post Stainless Steel	Class IIa		2023-09-18
55. 52 Surtex Fost Stanness Steel	Q01010199		2023-03-10
	Q01010199		

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







Class Cast Class Cast)-18)-18
TITS 4 - Surtex Post Stainless Steel Class III Q01010199 TITS 5 - Surtex Post Stainless Steel Class III Q01010199 TITS 6 - Surtex Post Stainless Steel Class III Q01010199 TITS 6 - Surtex Post Stainless Steel Class III Q01010199 TITS 13 - Surtex Post Stainless Steel Class III Q01010199 TITS 14 - Surtex Post Stainless Steel Class III Q01010199 TITS 15 - Surtex Post Stainless Steel Class III Q01010199 TITS 15 - Surtex Post Stainless Steel Class III Q01010199 TITS 16 - Surtex Post Stainless Steel Class III Q01010199 TITS 18 - Surtex Post Stainless Steel Class III Q01010199 TITS 18 - Surtex Post Stainless Steel Class III Q01010199 TITS 18 - Surtex Post Titanium intro kit Class III Q01010199 TITS 19 - Surtex Post Titanium complete Class III Q01010199 TITS 19 - Surtex Post Titanium complete Class III Q01010199 TITS 19 - Surtex Post Titanium assortment Class III Q01010199 TITS 19 - Surtex Post Titanium assortment Class III Q01010199 TITS 17 - Surtex Post Titanium assortment Class III Q01010199 TITS 17 - Surtex Post Titanium assortment Class III Q01010199 TITS 17 - Surtex Post Titanium assortment Class III Q01010199 TITS 17 - Surtex Posts Titanium Complete Class III Q01010199 TITS 17 - Surtex Posts Titanium Complete Class III Q01010199 TITS 18 - Surtex Posts, Titanium Class III Q01010199 TITS 19 - Surtex Posts, Titanium Class III Q01010199 TITS 2000-10010199	9-18
Q01010199 TT-S5 - Surtex Post Stainless Steel Class IIa Q01010199 TT-S6 - Surtex Post Stainless Steel Class IIa Q01010199 TT-SL3 - Surtex Post Stainless Steel Class IIa Q01010199 TT-SL4 - Surtex Post Stainless Steel Class IIa Q01010199 TT-SL5 - Surtex Post Stainless Steel Class IIa Q01010199 TT-SL5 - Surtex Post Stainless Steel Class IIa Q01010199 TT-SL5 - Surtex Post Stainless Steel Class IIa Q01010199 TT-SL6 - Surtex Post Stainless Steel Class IIa Q01010199 TT-SL6 - Surtex Post Stainless Steel Class IIa Q01010199 TT-SL6 - Surtex Post Stainless Steel Class IIa Q01010199 TT-SURTER - Surtex Post Stainless Steel Class IIa Q01010199 TT-SL7 - Surtex Post Titanium intro kit Class IIa Q01010199 TT-SL7 - Surtex Post Titanium starter Class IIa Q01010199 TT-SURTER - Surtex Post Titanium starter Class IIa Q01010199 TT-SURTER - Surtex Post Titanium complete Class IIa Q01010199 TT-SURTER - Surtex Post Titanium assortment Class IIa Q01010199 TT-Surtex Posts Titanium assortment Class IIa Q01010199 TT-Surtex Posts Titanium assortment Class IIa Q01010199 TT-Surtex Posts, Titanium Class IIa Q01010199 TT-SURTER - Surtex Posts, Titanium Class IIa Q01010199 TT-SURTER - Surtex Posts, Titanium Class IIa Q01010199 TT-SURTER - Surtex Posts, Titanium Class IIa Q01010199	9-18
Class IIa Q01010199 CT-SIG - Surtex Post Stainless Steel Class IIa Q01010199 CT-SIG - Surtex Post Stainless Steel Class IIa Q01010199 CT-SIG - Surtex Post Stainless Steel Class IIa Q01010199 CT-SIG - Surtex Post Stainless Steel Class IIa Q01010199 CT-SIG - Surtex Post Stainless Steel Class IIa Q01010199 CT-SIG - Surtex Post Stainless Steel Class IIa Q01010199 CT-SIG - Surtex Post Stainless Steel Class IIa Q01010199 CT-SIG - Surtex Post Stainless Steel Class IIa Q01010199 CT-SIG - Surtex Post Stainless Steel Class IIa Q01010199 CT-SIG - Surtex Post Stainless Steel Class IIa Q01010199 CT-SIG - Surtex Post Titanium intro kit Class IIa Q01010199 CT-SIG - Surtex Post Titanium starter Class IIa Q01010199 CT-SIG - Surtex Post Titanium complete Class IIa Q01010199 CT-SIG - Surtex Post Titanium complete Class IIa Q01010199 CT-SIG - Surtex Post Titanium complete Class IIa Q01010199 CT-SIG - Surtex Post Titanium complete Class IIa Q01010199 CT-SIG - Surtex Post Titanium complete Class IIa Q01010199 CT-SIG - Surtex Post Titanium complete Class IIa Q01010199 CT-SIG - Surtex Posts Titanium Class IIa Q01010199 CT-SIG - Surtex Posts Titanium Class IIa Q01010199 CT-SIG - Surtex Posts, Titanium Class IIa Q01010199	
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ST-B - Surtex Post Titanium complete Class IIa 2023-09 arter kit - reamers Q01010199 ST - Surtex Posts Titanium assortment Class IIa 2023-09 no reamers Q01010199 ST-EL3 - Surtex Posts, Titanium Class IIa Q01010199 ST-EL4 - Surtex Posts, Titanium Class IIa 2023-09 CT-EL4 - Surtex Posts, Titanium Class IIa	
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Tr-EL3 - Surtex Posts, Titanium Class IIa Q01010199 CT-EL3 - Surtex Posts, Titanium Class IIa Q01010199 CT-EL4 - Surtex Posts, Titanium Class IIa Q023-09	9-18
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CT-EL3 - Surtex Posts, Titanium Class IIa 2023-09-09-09-09-09-09-09-09-09-09-09-09-09-	
Q01010199 ST-EL4 - Surtex Posts, Titanium Class IIa 2023-09-	
ST-EL4 - Surtex Posts, Titanium Class IIa 2023-09	9-18
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ST-EL5 - Surtex Posts, Titanium Class IIa 2023-09	9-18
Q01010199	
ST-EL6 - Surtex Posts, Titanium Class IIa 2023-09	9-18
Q01010199	
ST-L1 - Surtex Posts, Titanium Class IIa 2023-09	
Q01010199	9-18
ST-L2 - Surtex Posts, Titanium Class IIa 2023-09	9-18
Q01010199	
ST-L3 - Surtex Posts, Titanium Class IIa 2023-09	9-18
Q01010199	9-18

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







Commonstrates	Product	Classification and EMDN	Intended use ¹	Date Added
Class III	TST-L4 - Surtex Posts, Titanium	Class IIa		2023-09-18
Color Class Is		Q01010199		
Class Ia	TST-L5 - Surtex Posts, Titanium	Class IIa		2023-09-18
Class Ila Class Class Ila Class Ila Class Class Ila Class Class Class Ila Class Clas		Q01010199		
Class Ila 2023-09-18 2023-09-18 2023-09-18 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 2023-09-18 201010199 2023-09-18 2023-09-18 201010199 2023-09-18 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 2023-09-18 201010199 2023-09-18 201010199 2023-09-18 2023-09-18 201010199 2023-09-18 2	TST-L6 - Surtex Posts, Titanium	Class IIa		2023-09-18
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Class Ia	TST-M1 - Surtex Posts, Titanium	Class IIa		2023-09-18
Class Ila		Q01010199		
TST-M3 - Surtex Posts, Titanium Class IIa 2023-09-18 TST-M4 - Surtex Posts, Titanium Class IIa 2023-09-18 Q01010199	TST-M2 - Surtex Posts, Titanium	Class IIa		2023-09-18
Class III		Q01010199		
TSF-M4 - Surtex Posts, Titanium Class IIa Q01010199 Class IIa Q01010	TST-M3 - Surtex Posts, Titanium	Class IIa		2023-09-18
Class III		Q01010199		
Class Ia Q01010199 Class Ia Q01010199	TST-M4 - Surtex Posts, Titanium	Class IIa		2023-09-18
Class Ila Class Ila Class Ila Class Ila Class Ila Control Class Control Class Ila Control Class Ila Control Class Control Class Ila Control Class Class Control Class Class Control Class Class Control Co		Q01010199		
Class Ila Q01010199 Clas	TST-M5 - Surtex Posts, Titanium	Class IIa		2023-09-18
Class Ia		Q01010199		
Class Ila	TST-M6 - Surtex Posts, Titanium	Class IIa		2023-09-18
Class Ila		Q01010199		
Class Ia Q01010199 Class Ia Q01010199	TST-S1 - Surtex Posts, Titanium	Class IIa		2023-09-18
Q01010199		Q01010199		
Class Ila Q01010199 Clas	TST-S2 - Surtex Posts, Titanium	Class IIa		2023-09-18
Class Ia		Q01010199		
TST-S4 - Surtex Posts, Titanium Class IIa Q01010199 TST-S5 - Surtex Posts, Titanium Class IIa Q01010199 TST-S6 - Surtex Posts, Titanium Class IIa Q01010199 TST-S6 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL3 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL3 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL4 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL5 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL5 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL5 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL6 - Surtex Posts, Titanium Class IIa Q01010199 PL L15 - Paralight 15 posts, with Class IIa Q01010199 PL L15 - Paralight 15 posts, with Class IIa Q01010199 PL L15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199	TST-S3 - Surtex Posts, Titanium	Class IIa		2023-09-18
Q01010199 Class IIa Q010		Q01010199		
TST-SS - Surtex Posts, Titanium Class IIa Q01010199 TST-S6 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL3 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL4 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL5 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL5 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL5 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL6 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL6 - Surtex Posts, Titanium Class IIa Q01010199 PLL15 - Paralight 15 posts, with Class IIa Q01010199 PL M15 - Paralight 15 posts, with Class IIa Q01010199 PL M15 - Paralight 15 posts, with Class IIa Q01010199 PL M15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q023-09-18 Marking cap Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q023-09-18 Marking cap Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q023-09-18 Marking cap Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q023-09-18 Marking cap Q01010199	TST-S4 - Surtex Posts, Titanium	Class IIa		2023-09-18
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TST-S6 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL3 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL4 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL5 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL5 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL6 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL6 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL6 - Surtex Posts, Titanium Class IIa Q01010199 PL L15 - Paralight 15 posts, with Class IIa Q01010199 PL M15 - Paralight 15 posts, with Class IIa Q023-09-18 Marking cap Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q023-09-18 Marking cap Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q023-09-18 Marking cap Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q023-09-18 Marking cap Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q023-09-18 Marking cap Q01010199	TST-S5 - Surtex Posts, Titanium	Class IIa		2023-09-18
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TST-SL3 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL4 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL5 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL5 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL6 - Surtex Posts, Titanium Class IIa Q01010199 TST-SL6 - Surtex Posts, Titanium Class IIa Q01010199 PL L15 - Paralight 15 posts, with Class IIa Q01010199 PL M15 - Paralight 15 posts, with Class IIa Q01010199 PL M15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199 PL S15 - Paralight 15 posts, with Class IIa Q01010199	TST-S6 - Surtex Posts, Titanium	Class IIa		2023-09-18
Q01010199 Class IIa Q010		Q01010199		
Q01010199 Class IIa Q010	TST-SL3 - Surtex Posts, Titanium	Class IIa		2023-09-18
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Q01010199 Class IIa 2023-09-18 Q01010199 Q01	TST-SL5 - Surtex Posts, Titanium			2023-09-18
Class Ila Q01010199 Q0				2020 00 20
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PL L15 - Paralight 15 posts, with				2020 00 10
PL L15 - Paralight 15 posts, with	Rasic LIDI-DI: 735011489PPI-PF5			
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PL XS15 - Paralight 15 posts, with Class IIa 2023-09-18	marking cap			
				2023-09-18
	marking cap	Q01010199		2023 03 10

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







Product Classification and EMDN Intended use¹ Date Added

Statt

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

Product list issue date: 18 September 2023



