

# EC CERTIFICATION

## FULL QUALITY ASSURANCE SYSTEM

### Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

#### Organization:

## Dentatus AB

Main Site: Finspångsgatan 42 SE-163 53 Spånga, Sweden

#### Product Category:

- Dental instruments
- Dental Implants
- Dental Posts
- Dental Implant procedure kits and accessories

For further identification of the products covered, see the MDD product list/product schedule.

#### Certificate Number:

41319232-02

#### Initial Certification Date:

12 April 2013

#### Certificate Valid from:

08 August 2018

#### Certificate Expiry Date:

12 April 2023



Ackred. nr 1003  
ISO/IEC 17021

  
**Peter Nermander**

Certification Authority MDD  
Intertek Semko AB, Kista, Sweden

16 August 2018

#### Signed Date

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The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.



Products included in the Certificate No: 41319232-01  
 Issued to: **Dentatus AB**  
 Finspångsgatan 42  
 SE-163 53 Spånga  
 Sweden

Product category	Type/Model designation	Classes	Sterile	GMDN code (not mandatory)	Date added
<b>Dental Implant procedure kits and accessories</b>					
	Atlas AK-1, AK-2, AR-110, AR-10, AK-3	Ila	No	44881	21 Aug 2015
	ANEW SK, SK-2, ST-S, SK-3, ST-L, SNL-x, SNP-2, SR-110-x, SR-111-x, SR-49, SR-61-x, SR-62-x, SR-45-x, SR-57- x, SR-59-x, CPR (-x= Quantity in package) ET-K, ET-190, ET-192	Ila	No	44881	21 Aug 2015
<b>Dental instruments</b>					
	AVA Tips Refills: AVA-1 -5, AVA-4A, AVA-5A, AVA-11 -15, AVA-21, AVA-23 -24, AVA-31 and AVA-41.	Ila	No	16460	12 Apr 2013
	Probos I Pathfinder x=Sizes 1-6 Refills: RUF-X/3 Assorted Package: RUF-1/6	Ila	No	16669	12 Apr 2013
	Probos II Reamer/Router y=Sizes 3-6 Refills: RUD-y/3 Assorted Package: RUD	Ila	No	16669	12 Apr 2013
	Standard Classic Diameters as above Short (28 mm): RUA-y/3 Long (33 mm): RUB-y/3 Assorted Packages: RUA-1/6 and RUB-1/6 Starter Kit (with Luminex): LX-NK Depth marked 7,9 and 11mm: RAM-T	Ila	No	16669	12 Apr 2013
	Standard Conical Diameters as above Short (28 mm): RUG-y/2 Long (33 mm): RUH-y/2	Ila	No	16669	12 Apr 2013
	Center Point (CePo) Drills for Dentatus 1.8, 2.2, 2.4 and 2.8 mm diam. implants System 1 and System 2: different depth markings	Ila	No	32390	12 Apr 2013

Product category	Type/Model designation	Classes	Sterile	GMDN code <small>(not mandatory)</small>	Date added
	Helix Classic Short (28 mm): RSA-y/3fp Long (33 mm): RSB-y/3fp Extralong (37 mm): RSC-y/2 y = Diameters: 1=1.05 mm 2=1.20 mm 3=1.35 mm 4=1.50 mm 5=1.65 mm 6=1.80 mm  Assorted Packages: RSA-123, RSA-345, RSA-456, RSB-123, RSB-345, RSB-456, RSC-123, RSC-345.	Ila	No	43311	12 Apr 2013
	Helix Conical Short (28 mm): RSG-y/3 Long (33 mm): RSH-y/3 Extralong (37 mm): RSI-y/2 Assorted Packages: RSG-345, RSG-456, RSH-345, RSH-456, RSI-345.	Ila	No	43311	12 Apr 2013
	Profin Starter Kit: PDX/SK PDX/CCK Contra-Angle only: PDX PROFIN-ET Starter Kit: PT-1, PT-3	Ila	No		02 Apr 2015
	Dentatus Mandrel MLR-RA, MLR-HP	Ila	No		12 Apr 2013
	EVA Tips x=quantity in package Polishing tips: EVA-2000/x, EVA-5000/x.,	Ila	No		12 Apr 2013
	LTA Tips Diamond grit sizes (in $\mu$ ): 15, 30, 50, 75, 100, 150. Tungsten grit sizes (in $\mu$ ): 36, 39. Assortments: LTA, LTA/U, LTA/S Refills: Standard Thin Spatula, 2-pack: LTA- $\mu$ /2 1-pack: LTA- $\mu$ Knife edge short, 2-pack: LTA-S $\mu$ /2 1-pack: LTA-S $\mu$ Paddle, 2-pack: LTA-D $\mu$ /2 1-pack: LTA-D $\mu$ Saw blade knife edge, 2-pack: LTA-T $\mu$ /2 1-pack: LTA-T $\mu$ . Ortho, stripping blades, 2-pack: LTA-L $\mu$ /2, LTA-R $\mu$ /2, LTA-LR $\mu$ . 1-pack: LTA-L $\mu$ , LTA-R $\mu$ . Shoulder/bevel: LTA-C50/2 and LTA-C50 Concave: LTA-E50/2 and LTA-E50.	Ila	No		12 Apr 2013

Product category	Type/Model designation	Classes	Sterile	GMDN code <small>(not mandatory)</small>	Date added
	LTA-F Flexible Tips Assortment: LTA-F set of 1 of each tip LTA-F50, LTA-F75 and LTA-F100 Refills, (2-pack): LTA-F50/2 - yellow shank. 50µ diamond grit LTA-F75/2 - golden shank. 75µ diamond grit. LTA-F100/2 - green shank. 100µ diamond grit Refills, (1-pack): LTA-F50 - yellow shank. 50µ diamond grit LTA-F75 - golden shank. 75µ diamond grit. LTA-F100 - green shank. 100µ diamond grit	Ila	No		01 Aug 2016
	LTA-P IPR Tips Assortment: LTA-P/SK Refills (2-pack): LTA-P25L/2, LTA-P25R/2, LTA-P3/2, LTA-P4/2, LTA-P5/2	Ila	No		27 Feb 2015
	Perio-Tor Tips z-Shapes: 1-6 Assortment: TOR-K (all shapes above) Refills: TOR-z (see shapes above) Rotary TOR, refills: TOR-7R, TOR- 8R and TOR-9R	Ila	No		12 Apr 2013
	Sizing Reamers for Dentatus 1.8, 2.2 and 2.4 mm diam. Implants	Ila	No		12 Apr 2013
<b>Dental posts</b>					
	Surtex Gold plated, Classic Gold Plated Lengths and diameters as Surtex Titanium Refills: RST-xy (15 pcs/pkg): Starter kits: Assortment Kit: RST-60 Complete Starter Kit: RST-B Extended Assortment Kit: RST-A Starter Refill Kit-no Reamers: RST Extended Starter Refill Kit-no Reamers: RST-240	Ila	No	38609	12 Apr 2013
	Surtex Stainless Steel, Classic Stainless Steel Lengths and diameters as Surtex Titanium Refills: SST-xy (12 pcs/pkg): Starter kits: Assortment Kit: SST-60 Complete Starter Kit: SST-B Starter Refill Kit-no Reamers: SST Starter Kit (with Luminex): LST-S	Ila	No	38609	12 Apr 2013

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
	<p>Surtex Titanium, Classic Titanium  x = Length: S= 7.8 mm, M=9.3 mm,  L=11.8 mm, EL=14.2 and SL=17 mm.  y = Diameter:  1=1.05 mm  2=1.20 mm  3=1.35 mm  4=1.50 mm  5=1.65 mm  6=1.80 mm</p> <p>Refills: TST-xy (15 pcs/pkg):  Starter kits:  Assortment Kit: TST-60  Complete Starter Kit: TST-B  Starter Refill Kit-no Reamers: TST  Assortment Kit w/ Helix Classic  Reamers TST-60H  Starter Kit (with Luminex): LST-T</p>	Ila	No	38609	12 Apr 2013
	<p>Luscent Anchor,  Non-metallic  Lengths: 15-19mm  Diameters: XXS, XS, S, M, L  (1,0-1,75mm)  Starter kits:  w/Standard Conical Reamers: LUC-  K3 and LUC-K9  w/Helix Conical Reamers: LUC-K10  Refills  LUC-/diameter/5 (5 pcs/pkg)  LUC-/diameter/15 (15pcs/pkg)  LUC-/diameter/30 (30 pcs/pkg)  Sample kit:  LUC-TS</p>	Ila	No	38609	12 Apr 2013
	<p>Twin Luscent Anchor, non-metallic  Length:16,7 mm  Diameters: XS, S, M, L (1,26-1,68  mm)  Starter kits:  w/ Standard Classic Reamers: LUT-  K1 and LUT-K3  w/ Helix Classic Reamers: LUT-K4  Refills  LUT-/diameter/5 (5 pcs/pkg)  LUT-/diameter/15 (15 pcs/pkg)  Sample kit:  LUT-PROV</p>	Ila	No	38609	12 Apr 2013

Product category	Type/Model designation	Classes	Sterile	GMDN code <small>(not mandatory)</small>	Date added
<b>Dental Implants</b>					
	ANEW ST-xyy-R ST-xyy-R-1 (single unit pack) xx= diameters (1.8-2.8 mm) y= lengths S, M, L (14-21 mm)	IIb	Yes	42354	12 Apr 2013
	Atlas AT-xyy-R xx= diameters (1.8-2.8 mm) y= lengths S, M, L (14-21 mm)	IIb	Yes	42354	12 Apr 2013

Date of Issue: February 20, 2019

**Intertek Semko AB**  
Notified Body MDD



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Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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