

CE CERTIFICATE OF CONFORMITY
WITH EUROPEAN DIRECTIVE



Certificate No.: EU1103426
Order No.: 188324

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Name and address of the manufacturer: Dentatus AB
Bromstensvägen 172, Box 8093
SE-163 55 Spånga,
Sweden

Device category: See Appendix 1 to this certificate

GMDN code: See Appendix 1 to this certificate

Models: See Appendix 1 to this certificate

Risk class as defined by the manufacturer: IIa and IIb

Standards/provisions: The audit of the quality system was based upon and assessed according to the provisions in Annex II of the EC-Directive 93/42/EEC, with the exemption of section 4.

Date of audit: 2011.02.02

Date of the end of the validity: 2013.04.11

Nemko EC notification No.: 0470

Remarks: This certificate replaces the certificate EU1103426 issued 2011.09.28

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Date of issue: 2012/11.07

Signature: Roy I. Holland

Lead auditor / Project Handler

Date of verification: 2012.11.07

Signature: Lars M. Forssander

Lead auditor / Project Handler

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Device category: See Appendix 1 to this certificate

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The certificate referred to above includes the following devices/models:

Type of device	Risk class	GMDN code
Dental rotary instruments, diamond coated	Ila	16670
Engine condensers and pluggers	Ila	16460
Dental oscillating and rotating instruments	Ila	16669, 44984, 44985
Engine dental reamers	Ila	16669
Gold plated dental posts	Ila	38609
Titanium dental posts	Ila	38609
Stainless steel dental posts	Ila	38609
Fiber glass dental posts	Ila	38609
Denture liners, elastic, long-term	Ila	34770
Dental handpieces	Ila	31823
Pin/post dental drill	Ila	43311
Surgical procedure kit	Ila	44883
Oscillating finishing and prophylactic dental instruments	Ila	38442

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Article number	Risk class	Type of product	Model	GMDN code
AR-110	Ila	Dental implant engine driver	ATLAS R/A Hpc. Implant Driver	33968
AT-18L-R	Iib	Dental implants, transgingival	ATLAS Implant Pack (2 units)	42354
AT-18M-R	Iib	Dental implants, transgingival	ATLAS Implant Pack (2 units)	42354
AT-18S-R	Iib	Dental implants, transgingival	ATLAS Implant Pack (2 units)	42354
AT-22L-R	Iib	Dental implants, transgingival	ATLAS Implant Pack (2 units)	42354
AT-22M-R	Iib	Dental implants, transgingival	ATLAS Implant Pack (2 units)	42354
AT-22S-R	Iib	Dental implants, transgingival	ATLAS Implant Pack (2 units)	42354
AT-24L-R	Iib	Dental implants, transgingival	ATLAS Implant Pack (2 units)	42354
AT-24M-R	Iib	Dental implants, transgingival	ATLAS Implant Pack (2 units)	42354
AT-24S-R	Iib	Dental implants, transgingival	ATLAS Implant Pack (2 units)	42354
AT-28M-R	Iib	Dental implants, transgingival	ATLAS Implant Pack (2 units)	42354
AT-28L-R	Iib	Dental implants, transgingival	ATLAS Implant Pack (2 units)	42354
AK-2-INTRO	Iib	Surgical procedure kit (Atlas system), incl. implants and reliner	ATLAS Intro Kit (incl. Implants and Tuf-Link)	44883 42354 34770
CPR	Ila	Dental implant suprastructure kit	ANEW Implant System, Component for Prov. Restorations	44881
MK-1	Iib	Dental implants, transgingival	MTI system, kit	42354
MK-2	Iib	Dental implants, transgingival	MTI system, kit	42354
MK-3	Iib	Dental implants, transgingival	MTI system, kit	42354
MK-NOW	Iib	Dental implants, transgingival	MTI system, kit	42354
MR-1006	Iib	Dental implants, transgingival	MTI system, implants	42354
MR-1041	Ila	Spiralled surgical drill	1.4 Center Point Pilot Drills LONG	32390
MR-1042	Ila	Spiralled surgical drill	1.4 Center Point Pilot Drills SHORT	32390
MR-1042/1	Ila	Spiralled surgical drill	1.4 Center Point Pilot Drills SHORT (single pack)	32390
MR-1045	Ila	Spiralled surgical drill	Center Point Profile Drills =2.2	32390
MR-1046	Ila	Spiralled surgical drill	Center Point Profile Drills =2.4	32390
MR-1141	Ila	Spiralled surgical drill	1.4 Center Point Pilot Drills LONG, System 2	32390
MR-1142	Ila	Spiralled surgical drill	1.4 Center Point Pilot Drills SHORT, System 2	32390
MR-1145	Ila	Spiralled surgical drill	Center Point Profile Drills =2.2, System 2	32390
MR-1146	Ila	Spiralled surgical drill	Center Point Profile Drills =2.4, System 2	32390
MR-1147	Ila	Spiralled surgical drill	Center Point Profile Drills =2.8, System 2	32390
MR-1050	Ila	Dental implant engine driver	MTI system, driver	33968
MR-1106	Iib	Dental implants, transgingival	MTI system, implants	42354
MR-1206	Iib	Dental implants, transgingival	MTI system, implants	42354
MR-2006	Iib	Dental implants, transgingival	MTI system, implants	42354
MR-2010	Ila	Dental implant suprastructure devices, temporary	MTI Modular Copings	44880
MR-2015	Ila	Dental implant suprastructure devices, temporary	MTI Singular Copings	44880
MR-2050	Ila	Dental implant suprastructure devices, temporary	MTI Ti Connective Bars	44880
MR-2106	Iib	Dental implants, transgingival	MTI system, implants	42354
MR-2206	Iib	Dental implants, transgingival	MTI system, implants	42354

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SK-22M	IIb	Dental implants	ANEW Implant System, kit	42354
SNL-2	IIa	Dental implants suprastructure kit	ANEW Laboratory Prosthetic Components	44881
SNP-2	IIa	Dental implants suprastructure kit	ANEW Clinical Prosthetic Components	44881
SR-18L	IIb	Dental implants	ANEW Implant System, refill kit	42354
SR-18M	IIb	Dental implants	ANEW Implant System, refill kit	42354
SR-18S	IIb	Dental implants	ANEW Implant System, refill kit	42354
SR-22L	IIb	Dental implants	ANEW Implant System, refill kit	42354
SR-22M	IIb	Dental implants	ANEW Implant System, refill kit	42354
SR-22S	IIb	Dental implants	ANEW Implant System, refill kit	42354
SR-24L	IIb	Dental implants	ANEW Implant System, refill kit	42354
SR-24M	IIb	Dental implants	ANEW Implant System, refill kit	42354
SR-24S	IIb	Dental implants	ANEW Implant System, refill kit	42354
SR-49	IIa	Dental implant suprastructure devices, permanent	2x ANEW indexed coping	44879
SR-57	IIa	Dental implant engine driver	ANEW R/A Hpc. Snap-In Driver	33968
SR-59	IIa	Dental rotating instrument	ANEW Hollow Trepine Drill	16669
SR-61	IIa	Dental implant suprastructure devices, permanent	ANEW Ti-Bar	44879
SR-62	IIa	Dental implant suprastructure devices, permanent	ANEW Screw-Cap white	44879
	IIa	Dental handpieces	ProfinPDX	45573
	IIa	Dental handpieces	ProfinPDX/SX	45573

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Article number	Risk class	Type of product	Model	GMDN code
ST-18L-R	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-18L-RD	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-18M-R	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-18M-RD	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-18S-R	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-18S-RD	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-22L-R	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-22L-RD	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-22M-R	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-22M-RD	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-22S-R	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-22S-RD	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-24L-R	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-24L-RD	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-24M-R	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-24M-RD	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-24S-R	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-24S-RD	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-18S-R-1	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-18M-R-1	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-18L-R-1	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-22S-R-1	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-22M-R-1	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-22L-R-1	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-24S-R-1	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354
ST-24M-R-1	IIb	Dental implants	ANEW Sterile Implant Pack (2 units) + Drill	42354
ST-24L-R-1	IIb	Dental implants	ANEW Sterile Implant Pack (2 units)	42354

Date of issue: 2012.11.07

Signature: Roy I. Holland

Lead auditor / Project Handler

Date of verification: 2012.11.07

Signature: Lars M. Forssander

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