

CE CERTIFICATE OF CONFORMITY
WITH EUROPEAN DIRECTIVE



Certificate No.: EU1104407
Order No.: 164354

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: ALPHADENT N.V.
Textielstraat 24,
B-8790 Waregem,
Belgium

Device category: See Appendix 1 to this certificate

GMDN code: See Appendix 1 to this certificate

Risk class as defined by the manufacturer: IIa

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: 2010-12-16

Date of the end of the validity: 2013-02-07

Nemko EC notification No.: 0470

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: 2011-05-20

Date of verification: 2011-05-20

Signature: Arild R. Hansgård
Lead auditor / Principal Engineer

Signature: Frank Skarpsno
Lead auditor / Project Handler

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Device category: Dental materials and Non-active dental equipment and instruments

Appendix 1: Page 1 of 1

The certificate referred to above includes the following devices:

MD scope expressions / code	Devices category	GMDN code
MD 0402 Dental materials	Dental prosthesis attachments	42296
	Dental post system	38609
	Dental implant suprastructure components	44879
	Bonding material for dental prosthetic attachments	34782
	Dental solders according to ISO 9333:1990	38780
	Dental metal bonding porcelain	34757
	Dental wrought alloy	38608
MD 0401 Non-active dental equipment and instruments	Dental alloy, casting, non-nobel according to ISO 22674:2006	16659
	Dental rotary instruments	16669, 16670, 33968

Date of issue: 2011-05-20

Date of verification: 2011-05-20

Arild Hansgård

Signature: Arild Hansgård
Lead auditor / Project Handler

Per *Frank Skarpsno*

Signature: Frank Skarpsno
Lead auditor / Project Handler