CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU1103419
Order No.: 182761

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:	Major Prodotti Dentari SpA Via Luigi Einaudi 23 I-10024 Moncalieri Italy
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
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:	2011.07.21-22
Date of the end of the validity:	2014.05.06
Nemko EC notification No.:	0470
Remarks:	This certificate replaces the certificate EU1103419 issued 2012.02.10

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: 2012.05.16

Signature: Roy I. Holland
Lead auditor / Project Handler

Date of verification: 2012.05.16

Signature: Lars M. Forssander
Lead auditor / Project Handler

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Via Luigi Einaudi 23
I-10024 Moncalieri
Italy

Device category: See Appendix 1 to this certificate

Appendix 1: Page 1 of 2

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

Device Category	GMDN code	Model
Synthetic polymer teeth	38643	Major Plus, Type 1 (anterior) Major Plus, Type 2 (posterior) Major Dent, Type 1 (anterior) Major Dent, Type 2 (posterior) Cristal RA/RD/RM Type 1 (anterior) Cristal RA/RD/RM Type 2 (posterior) Major Plus Comp. Type 2 (posterior) Bambino Tooth, Type 1 (anterior) Bambino Tooth, Type 2 (posterior) Super Lux, Type 1 (anterior) Super Lux, Type 2 (posterior) V-Dent, Type 1 (anterior) V-Dent, Type 2 (posterior) Major Plus WFA Type 2 (posterior) Major Plus WFA Comp.Type 2 (posterior) Major Plus Comp Type 1 (anterior) Major AF Comp, Type 1 (anterior) Major AF Comp, Type 2 (posterior)
Denture base polymer materials	16728	Major.base.20 Major.repair Major.skel Major Fibrils Perfect Resin rosa venata a caldo Perfect Resin rosa venata a freddo
Denture materials for relining, soft	17610	Major TotalSoft
Orthodontic polymer material	35310	major.ortho Perfect Resin ortho

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Italy

Device category: See Appendix 1 to this certificate

Appendix 1: Page 2 of 2

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

Dental temporary crown and bridge materials	31783	Temporary.cold.v Self Cure Dentine V-Dent Temporary Dentine
Dental crown and bridge materials	38781	Glass Composite Dentine Major C&B-V Dentine Perfect Resin bianca Major AF Comp
Dental ceramic	16187	Metal Ceramic, Stain set Metal Ceramic, Standard set Metal Ceramic, Top set

Date of issue: 2012.05.16

Signature: Roy I. Holland
Lead auditor / Project Handler

Date of verification: 2012.06.16

Signature: Lars M. Forssander
Lead auditor / Project Handler