

EC-CERTIFICATE

ISSUED BY NORDIC DENTAL CERTIFICATION - NOTIFIED BODY FOR THE COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES. NOTIFIED BODY NUMBER 0510.

- No. 0329 -

It is hereby declared that, on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, adequate confidence has been provided that

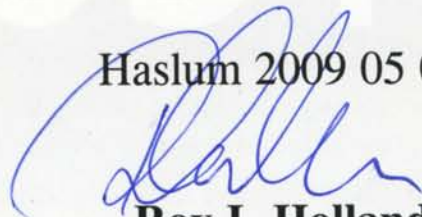
Major Prodotti Dentari SpA
Via Luigi Einaudi 23
I-10024 Moncalieri, Italy

has instituted a quality system in conformity with the requirements in Annex II, clause 3, of Council Directive 93/42/EEC for the products/product groups specified on the attached schedule and is for these products/product groups hereby granted the right to affix the CE marking of conformity, accompanied by the notified body identification number of NORDIC DENTAL CERTIFICATION, 0510.

Audit report no: C-0456-I1/08

This EC-CERTIFICATE is valid until 2014 05 06 provided that surveillance confirms continued conformity with the requirements of Council Directive 93/42/EEC.

Haslum 2009 05 06



Roy I. Holland
Director

NORDIC DENTAL CERTIFICATION

Kirkeveien 71B • N-1344 Haslum • Norway
Org.no.: NO 985 894 906

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issued 2009 05 06 (ver. 1) to
EC-CERTIFICATE no. 0329

Supplementary Information to EC-CERTIFICATE no. 0329, issued 2009.05.06 to

Major Prodotti Dentari SpA
Via Luigi Einaudi 23, I-10024 Moncalieri, Italy

The certificate is valid for the following products/product groups:

	<u>GMDN code</u>
Synthetic polymer teeth, comprising of the following products:	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)	
Denture base polymer materials, comprising of the following products:	16728
Major.base.20	
Major.repair	
Major.skel	
Major Fibrils	
Denture materials for relining, soft, comprising of the following products:	17610
Major TotalSoft	
Orthodontic polymer material, comprising of the following products:	35310
major.ortho	
Dental temporary crown and bridge materials, comprising of the following products:	31783
Temporary.cold.v	
Self Cure Dentine	
V-Dent Temporary Dentine	

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GMDN code

**Dental crown and bridge materials,
comprising of the following products:**

Glass Composite Dentine
Major C&B-V Dentine

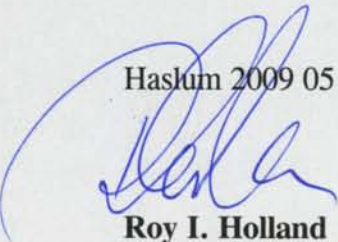
38781

Dental ceramic, comprising of the following products:

Metal Ceramic, Stain set
Metal Ceramic, Standard set
Metal Ceramic, Top set

16187

Haslum 2009 05 06



Roy I. Holland

Director, NORDIC DENTAL CERTIFICATION

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