CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU1212401
Order No.: 182661

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 CZ s.r.o. Lidická 1 568 02 Svitavy, Czech Republic
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 V of the EC-Directive 93/42/EEC.
Date of audit:	2012.06.18
Date of the end of the validity:	2018.01.16
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: 2013.01.16

Signature: Roy I. Holland
Lead auditor / Project Handler

Date of verification: 2013.01.16

Signature: Lars M. Forssander
Lead auditor / Project Handler

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Lidická 1
568 02 Svitavy, Czech Republic

Device category: See Appendix 1 to this certificate

Appendix 1: Page 1 of 1

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

Devices / GMDN Codes:	*Models*
Polymer denture teeth GMDN code: 38643	Super Lux, Type 1 (anterior) Super Lux, Type 2 (posterior)

Date of issue: 2013.01.16

Signature: Roy I. Holland
Lead auditor / Project Handler

Date of verification: 2013.01.16

Signature: Lars M. Forssander
Lead auditor / Project Handler