

EC-CERTIFICATE

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

- No. 0280/2 -

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

Super Lux, Type 1

intended for use as artificial teeth in the fabrication of

dental prostheses

(GMDN code: 38643)

manufactured by

Major CZ s.r.o.

Lidická 1, 568 02 Svitavy, Czech Republic

is in conformity with the requirements of Council Directive 93/42/EEC.

Coupling of this EC-CERTIFICATE with an EC declaration of conformity as set out in Annex VII of Council Directive 93/42/EEC, gives the licensee the right to affix the **CE** marking of conformity, accompanied by the notified body identification number of NORDIC DENTAL CERTIFICATION, 0510.

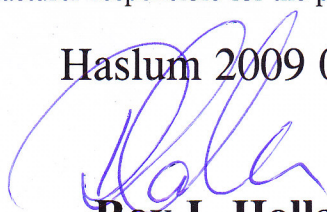
The examination includes product sample testing (test reports 0001/97, 057/99, and 0016G/01, 012/05, 009/06, 065/07, 061/08, and 010/09).

This EC-CERTIFICATE is valid until 2014 03 11 provided that surveillance confirms continued fulfillment of the requirements of Council Directive 93/42/EEC.

This EC-CERTIFICATE is no longer valid if any of the following occurs:

- the composition of the product is changed
- the structure of the product is changed
- the intended use is changed
- the name of the product is changed
- the licensee or manufacturer responsible for the product is changed.

Haslum 2009 03 11


Roy I. Holland
Director

Initial certification date:
2004 04 08

NORDIC DENTAL CERTIFICATION

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Org.no.: NO 985 894 906