# EC-CERTIFICATE

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

#### - No. 0093/3 -

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

### Major Dent, Type 1

intended for use as artificial teeth in the manufacture of dental prostheses

(GMDN code: 38643) manufactured by

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

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 C€ marking of conformity, accompanied by the notified body identification number of NORDIC DENTAL CERTIFICATION, 0510.

The examination includes product sample testing (test reports 0030/97 and 016A/01).

This EC-CERTIFICATE is valid until 2013 01 14 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This EC-CERTIFICATE is no longer valid if any of the following occurs: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 2008 01 14

Roy I. Holland Director

Initial certification date: 1998 01 14

## NORDIC DENTAL CERTIFICATION

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

# EC-CERTIFICATE

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

#### - No. 0094/3 -

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

### Major Dent, Type 2

intended for use as artificial teeth in the manufacture of dental prostheses

(GMDN code: 38643) manufactured by

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

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 C€ marking of conformity, accompanied by the notified body identification number of NORDIC DENTAL CERTIFICATION, 0510.

The examination includes product sample testing (test reports 0004/97 and 016B/01).

This EC-CERTIFICATE is valid until 2013 01 14 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 2008 01 14

## Roy I. Holland

Director

Initial certification date: 1998 01 14

## NORDIC DENTAL CERTIFICATION

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