

# EC-CERTIFICATE

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

- No. 0158/2 -

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

## **Resin System Skel**

in the variants listed in the supplement to this EC-CERTIFICATE

**intended for use as denture base material**

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 CE marking of conformity, accompanied by the notified body identification number of NIOM, 0510.

The examination includes product sample testing (test report 0131/97).

This EC-CERTIFICATE is valid until 2008 06 30 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This EC-CERTIFICATE is no longer valid if any of the following occurs: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 2003 06 30



**Roy I. Holland**

Head of NIOM CERTIFICATION



**SCANDINAVIAN INSTITUTE OF DENTAL MATERIALS**

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Supplementary Information to EC-CERTIFICATE no. 0158, for

**Resin System Skel**

**intended for use as denture base material**

manufactured by

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

The certificate is valid for the following product variants:

Pink (60)  
Veined pink (60 LV)

Haslum 2003/06/30

  
**Roy I. Holland**  
Head of NIOM CERTIFICATION

