

EC-CERTIFICATE

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

- No. 0293 -

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.skel

intended for use as denture base material

(GMDN code: 16728)

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 CERTIFICATION, 0510.

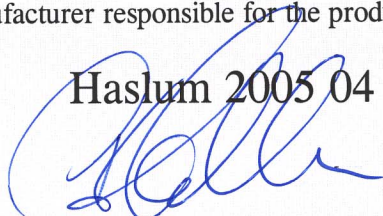
The examination includes product sample testing (test report 080/04).

This EC-CERTIFICATE is valid until 2010 04 19 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This EC-CERTIFICATE is no longer valid if any of the following occurs: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 2005 04 19



Roy I. Holland

Director, NIOM CERTIFICATION

NIOM CERTIFICATION

Kirkeveien 71B • P.O.Box 70 • N-1305 Haslum • Norway
Org.no.: NO 985 894 906