

EC-CERTIFICATE

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

- No. 0112/2 -

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

major.ortho

intended for use as base for dental orthodontic appliances

manufactured by

Major Prodotti Dentari SpA
v. L. 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.

This EC-CERTIFICATE is valid until 2003 04 27 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This EC-CERTIFICATE is no longer valid if any of the following occurs: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 2002 10 13



Roy I. Holland

Head of NIOM CERTIFICATION



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