EC-CERTIFICATE

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

- No. 0195/2 -

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

Valplast

intended for use as base material for dentures and partials

manufactured by

Valplast International Corporation 34-30 31st Street, Long Island City, NY 11106, USA

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 NIOM, 0510.

The examination includes product sample testing (test reports 0084/98, 0016/00, 045/01, 083/02, and 014/04).

This EC-CERTIFICATE is valid until 2009 02 26 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This EC-CERTIFICATE is no longer valid if any of the following occurs: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 2004 04/08

Roy I. Holland

Head of NIOM CERTIFICATION

NIOM

SCANDINAVIAN INSTITUTE OF DENTAL MATERIALS

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