

CERTIFICATE

Number: 2115569CE01



CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

Sumipro Submicron Lathing B.V.

Bedrijvenpark Twente 323

7602 KL Almelo

The Netherlands

For the product category:

Rigid and Soft Contact Lenses

KEMA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2115569CN, initially dated June 24, 2008

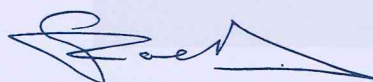
KEMA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex II for class IIa products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. The necessary information and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: May 15, 2012

Issued for the first time: June 24, 2008

Reissued: May 13, 2009

KEMA Quality B.V.

drs. G.J. Zoetbrood
Managing Directordr. ir. G.W. Bos
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

KEMA Medical

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