

CERTIFICATE

CE MARKING OF CONFORMITY

MEDICAL DEVICES

Number: **2061421CE01**

Issued to:

NovoSci Corp

**2828 North Crescent Ridge Drive
The Woodlands, TX 77381
USA**

For the product category:

Non-Active Extracorporeal Cardiopulmonary By-Pass Products Cannulae and Accessories

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 Agreement 2018969, initially dated April 1, 2002

Certification Notice 2018969CN, initially dated June 5, 2002

Addendum, initially dated: June 15, 2004

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 14 June 1993 concerning medical devices, and that for the above mentioned product category the Conformity Assessment Procedure Annex V, for Class IIa products in combination with Annex VII, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of 14 June 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: **June 1, 2007**

Issued for the first time: June 15, 2004



drs. ing. E.J. Duim
Managing Director

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ADDENDUM

CE MARKING OF CONFORMITY

MEDICAL DEVICES

Belonging to certificate: **2061421CE01**

**Non-Active Extracorporeal Cardiopulmonary By-Pass Products
Cannulae and Accessories**

Issued to:

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USA

This certificate covers the following product (s):

Air Aspirator Needles (Class IIa)
Perfusion Adapter Sets (Class IIa)
Pressure MonITORR (Class IIa)
Venous Reservoir (Class IIa)
Vessel Clamps (Class IIa)
Suckers and Sump Sets (Class IIa)
Arterial Filters (Class IIa)

Initial date: June 15, 2004
Revision date:



drs. ing. E.J. Duim
Managing Director

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