

# CERTIFICATE

Number: 2061421CE01

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

**NovoSci Corporation**

2021 Airport Road  
Conroe, TX 77301  
USA

For the product category:

**Medical Devices Used in Cardiovascular and Peripheral Vascular Surgical Procedures and Critical Care and Accessories**

DEKRA 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 2018969CN, initially dated June 5, 2002  
Addendum, initially dated June 15, 2004**

DEKRA 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 V in combination with Annex VII for class 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: **September 1, 2013**

Issued for the first time: June 15, 2004

Revision date: August 30, 2011

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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All testing, inspection, auditing and certification activities of the former KEMA Quality are an integral part of the DEKRA Certification Group.

# ADDENDUM

Belonging to certificate: **2061421CE01**

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

**Medical Devices Used in Cardiovascular and Peripheral Vascular Surgical Procedures and Critical Care and Accessories**

Issued to:

**NovoSci Corporation**

**2021 Airport Road  
Conroe, TX 77301  
USA**

This certificate covers the following product(s):

Air Aspirator Needles (Class IIa)  
Perfusion Adapter Sets (Class IIa)  
Pressure MoniTORR (Class IIa)  
Vessel Clamps (Class IIa)  
Suckers and Sump Sets (Class IIa)

Initial date: June 15, 2004

Revision date: September 22, 2010

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan  
Certification Manager

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