

CERTIFICATE

Number: **2022466CE02**

CE MARKING OF CONFORMITY MEDICAL DEVICES AND ANIMAL TISSUE DIRECTIVE

Issued to:

Scion Cardio-Vascular, Inc
14253 S.W. 119 Ave.
Miami, FL 33186
USA

For the product category:

Non-Woven Hydrophilic Wound Dressings

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 2022466CN, initially dated October 15, 2002
Addendum, initially dated October 15, 2002

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 and Animal Tissue directive, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex V in combination with Annex III for Class III products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. Additionally, KEMA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of the Directive 2003/32/EC of April 23, 2003 concerning medical devices manufactured utilising tissue of animal origin. 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, 2011**

Issued for the first time: October 15, 2002

Renewed: September 22, 2009

KEMA Quality B.V.



drs. G.J. Zoetbrood
Managing Director



M. McCann
Certification Manager

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KEMA Medical

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ADDENDUM

Belonging to certificate: **2022466CE02**

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CE MARKING OF CONFORMITY MEDICAL DEVICES AND ANIMAL TISSUE DIRECTIVE

Non-Woven Hydrophilic Wound Dressings

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Scion Cardio-Vascular, Inc

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Miami, FL 33186

USA

This certificate covers the following product(s):

CLO-SUR PAD (Class III)

CLO-SUR plus PAD (Class III)

Initial date: October 15, 2002

Revision date: August 20, 2008

KEMA Quality B.V.



drs. G.J. Zoetbrood
Managing Director



M. McCann
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