CERTIFICATE

Number: 2116857CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Issued to:

Biosensors Europe SA
Rue de Lausanne 29
1110 Morges
Switzerland

For the product category:

Drug Eluting Stent System for Coronary Use

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 2116857CN, initially dated 15 July 2008
Addendum, initially dated 15 July 2008

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 II 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. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II, section 4 is mandatory. 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: 15 July 2014
Issued for the first time: 15 July 2008
Reissued: 15 July 2011

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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

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ADDENDUM

Belonging to certificate: 2116857CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Drug Eluting Stent System for Coronary Use

Issued to:

Biosensors Europe SA
Rue de Lausanne 29
1110 Morges
Switzerland

This certificate covers the following product(s):

BioMatrix Drug Eluting Stent System
BioMatrix Flex Drug Eluting Stent System

BioMatrix:	BioMatrix Flex:
6 crown: **Diameter varies** between 2.25 to 3.25 mm. Length varies between 8 to 28 mm. 9 crown: Diameter 3,50 and 4,00 mm. Length varies between 8 to 28 mm (one size 23 mm instead of 24 mm for the Flex)	6 crown: Diameter varies between 2.25 to 3.00 mm. Length varies between 8 to 28 mm. Diameter varies between 2.50-3.00 mm. Length varies between 33 and 36 mm. 9 crown: Diameter 3,50 and 4,00 mm. Length varies between 8 to 28 mm. Diameter 3.5 mm. Length varies between 33 and 36 mm.

Initial date: 15 July 2008
Revision date: 14 September 2010

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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