CERTIFICATE

Number: 2116857DE02

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Issued to:

Biosensors Europe SA
Rue de Lausanne 29
1110 Morges
Switzerland

For the product(s) / product category:

BioMatrix Flex
Drug eluting Stent System for Coronary use

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.

Documents, that form the basis of this certificate:

Certification Notice 2116857CN, initially dated 15 July 2008
CE Marking of Conformity 2116857CE01

DEKRA hereby certifies 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 the design of the product(s) falling within the product category mentioned above, conforms to the provisions of the Council Directive 93/42/EEC of June 14, 1993, in accordance with Annex II, section 4 of this Directive. The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and 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: 18 January 2010
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.

DEKRA Certification B.V.Utrechtseweg 310, 6812 AR Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 26 356 2000 F +31 26 352 5800 www.dekra-certification.com Company registration 09085396