BIOSENSORS
INTERNATIONAL

DECLARATION OF CONFORMITY

We, Biosensors Europe SA
Rue de Lausanne 29
1110 Morges
Switzerland

declare on our own responsibility that

the medical devices **BioMatrix Drug Eluting Coronary Stent System**
(Catalogue number: see annex 2)
BioMatrix Flex Drug Eluting Coronary Stent System
(Catalogue number: see annex 1)

meet all applicable requirements of the Medical Directive 93/42/EEC Annex II, section 4 and Annex II, section 3 and of the Medical Directive 2007/47.

Classification:	Class III based on Annex IX, Rules 8 and 13 of the Medical Directive 93/42/EEC

Applied standards:

EN ISO 14971:2009	Medical devices - Application of Risk Management to medical devices
EN ISO 11137-1:2006 /AC:2009	Sterilization of Medical devices by irradiation – requirements for the development, validation and routine control of sterilization process for medical devices
EN ISO 11137-2:2009	Sterilization of health care products – Radiation: Establishing the sterilization dose
EN ISO 14299: 2004	Non-active surgical implants – Particular requirements for cardiac and vascular implants – Specific requirements for arterial stents
EN 980: 2008	Graphic Symbols for Use in the Labeling of Medical Devices
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO 10993-1:2009*	Biological Evaluation of Medical Device

*and all applicable parts

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v04 dated 15.09.10
(supersedes v03 dated 12.07.10)

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Name, address of Notified body:	KEMA Quality B.V. Utrechtsweg 310 6812 AR Arnhem The Netherlands
EC Notified Body Identification Number	0344
Conformity assessment procedures	MDD, Annex II.3 CE marking of Conformity certificate **2116857CE01** issued on July 15, 2008 and revised on December 2008, with Addendum revised on September 14, 2010 MDD Annex II.4 EC Design Examination certificates: **2116857DE01** issued on July 15, 2008 and revised on January 18, 2010 **2116857DE02** issued on January 18, 2010 and revised on September 14, 2010
BioMatrix **First Lot number under this DOC**	W10080188
BioMatrix **Release date of the first lot**	September 15, 2010
BioMatrix Flex **First Lot number under this DOC**	K10090001
BioMatrix Flex **Release date of the first lot**	September 15, 2010

Place:	Biosensors Europe SA	Date: September 15, 2010
Name:	Daniel Shoukier	Signature:
Title:	Regulatory Affairs Director	

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Annex 1: BioMatrix Flex Product Codes (Part Numbers)

BioMatrix Flex Product Code	Nominal Stent Inner Diameter (mm)	Stent Length (mm) *(unexpanded)*
BMX-2208	2.25	8
BMX-2211	2.25	11
BMX-2214	2.25	14
BMX-2218	2.25	18
BMX-2224	2.25	24
BMX-2228	2.25	28
BMX-2508	2.5	8
BMX-2511	2.5	11
BMX-2514	2.5	14
BMX-2518	2.5	18
BMX-2524	2.5	24
BMX-2528	2.5	28
BMX-2533	2.5	33
BMX-2536	2.5	36
BMX-2708	2.75	8
BMX-2711	2.75	11
BMX-2714	2.75	14
BMX-2718	2.75	18
BMX-2724	2.75	24
BMX-2728	2.75	28
BMX-2733	2.75	33
BMX-2736	2.75	36
BMX-3008	3.0	8
BMX-3011	3.0	11
BMX-3014	3.0	14
BMX-3018	3.0	18
BMX-3024	3.0	24
BMX-3028	3.0	28
BMX-3033	3.0	33
BMX-3036	3.0	36
BMX-3508	3.5	8
BMX-3511	3.5	11
BMX-3514	3.5	14
BMX-3518	3.5	18
BMX-3524	3.5	24
BMX-3528	3.5	28
BMX-3533	3.5	33
BMX-3536	3.5	36
BMX-4008	4.0	8
BMX-4011	4.0	11
BMX-4014	4.0	14
BMX-4018	4.0	18
BMX-4024	4.0	24
BMX-4028	4.0	28

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