EC DESIGN-EXAMINATION CERTIFICATE

Number: 2116857DE04

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

Biosensors Europe SA

Rue de Lausanne 29
1110 Morges
Switzerland

For the product

Drug Coated Stent System for Coronary use

Documents, that form the basis of this certificate:

Certification Notice 2116857CN, initially dated 15 July 2008
CE Marking of Conformity 2116857CE05
Addendum, initially dated 25 January 2013

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
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:	1 February 2023
Issued for the first time:	25 January 2013
Revised:	6 July 2016
Reissued:	1 February 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2116857DE04

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Drug Coated Stent System for Coronary use

Issued to:

Biosensors Europe SA
Rue de Lausanne 29
1110 Morges
Switzerland

This certificate covers the following product(s):

BioFreedom™ - Drug Coated Coronary Stent System

Stent lengths (mm) / Stent nominal diameters (mm)	8	11	14	18	24	28	33	36
2.25	BFR1-2208	BFR1-2211	BFR1-2214	BFR1-2218	BFR1-2224	BFR1-2228		
2.5	BFR1-2508	BFR1-2511	BFR1-2514	BFR1-2518	BFR1-2524	BFR1-2528	BFR1-2533	BFR1-2536
2.75	BFR1-2708	BFR1-2711	BFR1-2714	BFR1-2718	BFR1-2724	BFR1-2728	BFR1-2733	BFR1-2736
3.0	BFR1-3008	BFR1-3011	BFR1-3014	BFR1-3018	BFR1-3024	BFR1-3028	BFR1-3033	BFR1-3036
3.5	BFR1-3508	BFR1-3511	BFR1-3514	BFR1-3518	BFR1-3524	BFR1-3528	BFR1-3533	BFR1-3536
4.0	BFR1-4008	BFR1-4011	BFR1-4014	BFR1-4018	BFR1-4024	BFR1-4028		

Initial date: 25 January 2013
Revision date: 6 July 2016

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drs. G.J. Zoetbrood
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ADDENDUM

Belonging to certificate: 2116857DE04

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Drug Coated Stent System for Coronary use

Issued to:

Biosensors Europe SA
Rue de Lausanne 29
1110 Morges
Switzerland

This certificate covers the following product(s):

LUMENO™ Free - Drug Coated Coronary Stent System

Stent lengths (mm) / Stent nominal diameters (mm)	8	11	14	18	24	28	33	36
2.25	LUFR2208	LUFR2211	LUFR2214	LUFR2218	LUFR2224	LUFR2228		
2.5	LUFR2508	LUFR2511	LUFR2514	LUFR2518	LUFR2524	LUFR2528	LUFR2533	LUFR2536
2.75	LUFR2708	LUFR2711	LUFR2714	LUFR2718	LUFR2724	LUFR2728	LUFR2733	LUFR2736
3.0	LUFR3008	LUFR3011	LUFR3014	LUFR3018	LUFR3024	LUFR3028	LUFR3033	LUFR3036
3.5	LUFR3508	LUFR3511	LUFR3514	LUFR3518	LUFR3524	LUFR3528	LUFR3533	LUFR3536
4.0	LUFR4008	LUFR4011	LUFR4014	LUFR4018	LUFR4024	LUFR4028		

Initial date: 6 July 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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