AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat de conofmritate CE DE
I.3. Certificatul CE	Certificat de conofmirtate CE FQA
I.2. Declarația de conformitate CE	Declaratia de conofmritate CE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
		neoflex								
DM000302625	STENTURI CORONARIENE CU ELIBERARE DE SUBSTANȚĂ ANTIRESTENOZĂ-BIOLIMUS	BIOMATRIX NEOFLEX	3.0 x 28 mm	BMXP-3028	Elvetia	BIOSENSORS EUROPE SA	CLASDAC S.R.L.	Rg04-000013	25-01-2021	
DM000302632	STENTURI CORONARIENE CU ELIBERARE DE SUBSTANȚĂ ANTIRESTENOZĂ-BIOLIMUS	BIOMATRIX NEOFLEX	3.5 x 24 mm	BMXP-3524	Elvetia	BIOSENSORS EUROPE SA	CLASDAC S.R.L.	Rg04-000013	25-01-2021	
DM000302637	STENTURI CORONARIENE CU ELIBERARE DE SUBSTANȚĂ ANTIRESTENOZĂ-BIOLIMUS	BIOMATRIX NEOFLEX	4.0 x 11 mm	BMXP-4011	Elvetia	BIOSENSORS EUROPE SA	CLASDAC S.R.L.	Rg04-000013	25-01-2021	
DM000302607	STENTURI CORONARIENE CU ELIBERARE DE SUBSTANȚĂ ANTIRESTENOZĂ-BIOLIMUS	BIOMATRIX NEOFLEX	2.5 x 18 mm	BMXP-2518	Elvetia	BIOSENSORS EUROPE SA	CLASDAC S.R.L.	Rg04-000013	25-01-2021	
DM000302629	STENTURI CORONARIENE CU ELIBERARE DE SUBSTANȚĂ ANTIRESTENOZĂ-BIOLIMUS	BIOMATRIX NEOFLEX	3.5 x 11 mm	BMXP-3511	Elvetia	BIOSENSORS EUROPE SA	CLASDAC S.R.L.	Rg04-000013	25-01-2021	
DM000302633	STENTURI CORONARIENE CU ELIBERARE DE SUBSTANȚĂ ANTIRESTENOZĂ-BIOLIMUS	BIOMATRIX NEOFLEX	3.5 x 28 mm	BMXP-3528	Elvetia	BIOSENSORS EUROPE SA	CLASDAC S.R.L.	Rg04-000013	25-01-2021	
DM000302634	STENTURI CORONARIENE CU ELIBERARE DE SUBSTANȚĂ ANTIRESTENOZĂ-BIOLIMUS	BIOMATRIX NEOFLEX	3.5 x 33 mm	BMXP-3533	Elvetia	BIOSENSORS EUROPE SA	CLASDAC S.R.L.	Rg04-000013	25-01-2021	
	STENTURI									

DECLARATION OF CONFORMITY

We

Biosensors Europe SA
Rue de Lausanne 29
1110 Morges
Switzerland

declare on our own responsibility that the medical devices:

BioMatrix Flex and BioMatrix NeoFlex
Drug Eluting Coronary Stent System

(Catalogue number: see Annex 1 and 2)

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

Classification	Class III based on Annex IX, Rules 8 and 13 of the Medical Device Directive 93/42/EEC
GMDN code	58771
Product Family	Drug eluting coronary artery stent system, bioabsorbable-polymer coated
Applied standards	Refer to Annex 3 for the standard list
Notified body	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem The Netherlands
EC Notified Body Identification Number	0344
Conformity assessment procedures	MDD, Annex II, Section 3 and 4, Full Quality Assurance System (CE) and EC Design Examination (DE) certificates: - **2116857CE01** issued on 15 July 2008, reissued on July 17, 2017 - **2116857DE02** issued on 18 January 2010, reissued on 17 July 2017 - **2116857DE05** issued on 16 May 2013, reissued on 3rd July 2019

Place	Biosensors Europe SA
Date	08 July 2019
Name	Guylaine Dudley-Casses
Title	Regulatory Affairs Director
Signature	

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template ID-10023 rev. 05

Annex 1

BioMatrix Flex – Model references (part numbers)

BioMatrix Flex *Model reference*	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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Annex 2

BioMatrix NeoFlex – Model references (part numbers)

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

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Annex 3

Standard list (ST-0006 and ST-0007)

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The Standards listed below were taken into consideration in the manufacture of BioMatrix Flex products.

1. STANDARDS FOR COMPLIANCE

European Directive	Document
Council Directive 93/42/EEC	Medical Devices Directive
2007/47/EC	Amends Directive 93/42/EEC
2001/20/EC	Clinical Trials Directive
2001/83/EC	Medicinal Products for Human Use
94/62/EC	Packaging and Packaging Waste Directive
Regulation (EC) 1272/2008 as per amended by Commission Regulation (EU) 2017/542	Classification, packaging and labelling of dangerous preparations
1907/2006/EC	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Amends Directive 1999/45/EC

European Medical Device Guidance	Document
MEDDEV 2.1/3 rev.3:2009	Borderline products, drug-delivery products and medical devices incorporating,as integral part, an ancillary medicinal substance or an ancillary human blood derivative
MEDDEV 2.7/1 rev.4: 2016	Clinical evaluation: Guide for manufacturers and notified bodies
MEDDEV 2.7/1 Appendix 1 (December 2008)	Clinical Evaluation of Coronary Stents
MEDDEV 2.12/1 rev.8: 2013	Medical devices vigilance system
MEDDEV 2.12/2 rev 2: 2012	Post Market Clinical Follow-Up Studies

EMEA (European Medicines Agency) Guidelines	
EMEA/CHMP/EWP/110540/07	Clinical and non-clinical evaluation during the consultation procedure on medicinal substances contained in drug-eluting (medicinal substance-eluting) coronary stents

International Conference on Harmonisation (ICH)	Document
ICH M2 EWG V.3.2.2	Electronic Common Technical Document Specification
ICH Topic M4Q	Common Technical Document for the Registration of Pharmaceuticals for Human Use - Quality
ICH Guideline: Q1A (R2):2003	Stability Testing of new Drug Substances and Products
ICH Guideline: Q1C:1996	Stability testing for new dosage forms
ICH Guideline: Q1D:2002	Bracketing And Matrixing Designs For Stability Testing Of New Drug Substance And Products

Harmonized standards under Directive 93/42/EEC for Medical devices	Title
EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices

Harmonized standards under Directive 93/42/EEC for Medical devices	Title
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4:2009	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2009	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
EN ISO 10993-11:2009	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2007)
EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2006/AC:2009	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 13485:2016	Medical Devices - Quality Management Systems - Requirements for regulatory purposes
EN ISO 14155:2011/AC:2011	Clinical investigation of medical devices for human subjects - Good clinical practice.
EN ISO 14630:2009	Non-active surgical implants - General requirements
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN 20594-1:1993/A1:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
EN ISO 25539-1:2009/AC:2011	Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses
EN ISO 25539-2:2009/AC:2011	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents
EN 62366:2008	Medical devices - Application of usability engineering to medical devices

Other European Standards	Title
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
EN ISO 14644-3:2005	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14644-4:2001	Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up
EN ISO 14644-5:2004	Cleanrooms and associated controlled environments - Part 5: Operations
EN ISO 14644-6:2007	Cleanrooms and associated controlled environments - Part 6: Vocabulary
EN ISO 14644-7:2004	Cleanrooms and associated controlled environments - Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
EN ISO 14644-8:2013	Cleanrooms and associated controlled environments - Part 8: Classification of airborne molecular contamination
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
EN ISO 14698-2:2003/AC:2006	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data

2. STANDARDS FOR REFERENCE PURPOSES ONLY

Other European Standards	Title
EN ISO 11137-3	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects
EN ISO 11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements
EN ISO 13355	Packaging - Complete, filled transport packages and unit loads – Vertical random vibration test
EN ISO 15225	Medical devices - Quality management - Medical device nomenclature data structure
EN ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories

ISTA Standards	Document
ISTA 7D	Thermal Controlled Transport Packaging for Parcel Delivery System Shipment

AAMI Standards	Document
AAMI TIR33	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose - Method VDmax

ASTM Standards	Document
ASTM D642-15	Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components and Unit Loads
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D4728-17	Standard Test Method for Random Vibration Testing of Shipping Containers
ASTM F88/F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Medical Device Packages
ASTM F2052-15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2079-09	Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents
ASTM F2081-06	Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents
ASTM F2119-07	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ASTM F2129-17b	Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
ASTM F2182-11a	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2394-07	Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System
ASTM F2477-07	Standard Test Methods for *in vitro* Pulsatile Durability Testing of Vascular Stents

3. OTHER REFERENCES

Other Standard	Document
ISO 5832-1	Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel
ISO 14001:2015	Environmental Management Systems

ECO	Rev.	Description of Change	Prepared By	Effective Date
ECO-12127	05	Included line extension: BioMatrix Flex BTK drug eluting peripheral stent system. Design and manufacturing process of BioMatrix Flex BTK and BioMatrix Flex are identical, the design performance testing including biocompatibility testing, pharmacokinetics and histopathology, coating durability and integrity, stent radiopacity, corrosion resistance, stent retention, MRI safety, balloon compliance and rated burst pressure, balloon fatigue, pushability, trackability, tensile testing, and flex-kink testing carried out for BioMatrix Flex is also applicable to BioMatrix Flex BTK.	Shermaine Png	10-Sep-2014
ECO-12573	06	Update of standards revision and separation into various sections as per ID.05.80	Sharon Tan	26-Jan-2015
ECO-13719	07	Update of standards revision, deletion of a superseded standard and cutting down the number of sections to the following: • Standards for Compliance • Standards for Reference purposes Only Added GHTF/SG3/N99-10	Roy Tay	23-Dec-2015
ECO-15444	08	Streamline to remove GHTF, ETO standards and add in updated guidances e.g. MEDDEV 2.7/1 rev.4: 2016 Remove BioMatrix, BioMatrix Flex BTK from ST-0006.	Thum Ee Lin	05-Jun-2017
ECO-18031	09	Update to current standards revision Moved ISO 15223-1 to Harmonised standards under Directive 93/42/EEC since it is now harmonized Removal of: MEDDEV 2.5/10: 2012 ICH Guideline: Q1E:2003 ICH Guidance Q3C (R4) EN 980: 2008 EN ISO 10555-1:2009 EN ISO 10993-9:2009 EN ISO 10993-16:2010 EN ISO 10993-17:2009 EN ISO 10993-18:2009 EN ISO 11138-2:2009 EN ISO 10555-4:2013 Addition of: 94/62/EC EN ISO 15223-1:2016 EN ISO 25539-1:2009/AC:2011 EN ISO 11137-3 EN ISO 11138-1 EN ISO/IEC 17025	Julie Vergez/ Annelise Bette	16-May-2019

		Updated ASTM Standards Deleted country/ Canada regulations Updated to add additional applicable references: ISO 5832-1 ISO 14001:2015		

The Standards listed below were taken into consideration in the manufacture of BioMatrix Flex+ products.
Commercial name: BioMatrix NeoFlex/LUMENO Flex.

1. STANDARDS FOR COMPLIANCE

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Council Directive 93/42/EEC	Medical Devices Directive
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94/62/EC	Packaging and Packaging Waste Directive
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EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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EN ISO 14155-:2011**/AC:2011**	Clinical investigation of medical devices for human subjects - Good clinical practice.
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EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN 20594-1:1993/AC:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
EN ISO 25539-1:2009/AC:2011	Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses
EN ISO 25539-2: 2009/AC:2011	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents
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EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
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EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
EN ISO 14644-3:2005	Cleanrooms and associated controlled environments - Part 3: Test methods

EN ISO 14644-4:2001	Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up
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EN ISO 14698-1:2003	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
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Other European Standards	Title
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EN ISO 11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements
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EN ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories

ASTM Standards	Document
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ASTM D4728-17	Standard Test Method for Random Vibration Testing of Shipping Containers
ASTM F88/F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Medical Device Packages
ASTM F2052-15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2079-09	Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents
ASTM F2081-06	Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents
ASTM F2119-07	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ASTM F2129-17b	Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
ASTM F2182-11a	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2394-07	Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System
ASTM F2477-07	Standard Test Methods for *in vitro* Pulsatile Durability Testing of Vascular Stents

ISTA Standards	Document
ISTA 7D	Thermal Controlled Transport Packaging for Parcel Delivery System Shipment

AAMI Standards	Document
AAMI TIR33	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose - Method VDmax

3. OTHER REFERENCES

Other Standard	Document
ISO 5832-1	Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel
ISO 14001:2015	Environmental Management Systems

Revision	Date	Description of Change	Prepared By
01	12-Nov-2013	Initial Release for standard compliance list of BioMatrix Flex+	Julie Heubi
02	26-Jan-2015	Rearranged the sections for the standards. Updated EN ISO 11137-2 and 11137-2	Huang Shu-Ying
03	04-Jan-2016	Updated standards revision and moved standards to appropriate sections. Deleted EN ISO 22442-2 & EN ISO 22442-3	Roy Tay
04	12-Feb-2019	Updated scope to reflect LUMENO Flex Updated standards revision Updated list to remove ethylene oxide sterilization standards: Deleted EN ISO 10993-7:2008/AC:2009 Deleted EN ISO 11135-1:2007 Deleted EN ISO 11138-2:2009 Updated to remove withdrawn standards: Deleted ISO 1707 Updated to remove other not applicable references Deleted EN ISO 10555-1:2019 Deleted EN ISO 10555-4:2013 Deleted EN ISO 14937:2009 Deleted EN ISO 10993-9:2009 EN ISO 10993-16:2010 Deleted ICH Guideline: Q1E:2003 Deleted ISTA 7E Deleted ISTA 2A Deleted country/US FDA regulations Updated to add additional applicable references: ISTA 7D ISO 5832-1 ISO 14001:2015	Annelise Bette
05	16-May-2019	Update release date/revision of Appendix 1 of Meddev MEDDEV 2.7/1 Update EN ISO 14155:2011 to EN 14155-:2011/AC:2011	Annelise Bette/ Julie Vergez

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2116857DE05

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 Eluting Stent System for Coronary use

Documents, that form the basis of this certificate:

Certification Notice 2116857CN, initially dated 15 July 2008
Addendum, initially dated 16 May 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: 26 May 2024
Issued for the first time: 16 May 2013
Revised: 6 July 2016
Reissued: 3 July 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2116857DE05

EC DESIGN-EXAMINATION
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 NeoFlex™ - Drug Eluting Coronary Stent System

Models

Stent lengths / *Stent Nominal diameter*	8 mm	11 mm	14 mm	18 mm	24 mm	28 mm	33mm	36mm
2,25 mm	BMXP-2208	BMXP-2211	BMXP-2214	BMXP-2218	BMXP-2224	BMXP-2228		
2,5 mm	BMXP-2508	BMXP-2511	BMXP-2514	BMXP-2518	BMXP-2524	BMXP-2528	BMXP-2533	BMXP-2536
2,75 mm	BMXP-2708	BMXP-2711	BMXP-2714	BMXP-2718	BMXP-2724	BMXP-2728	BMXP-2733	BMXP-2736
3,0 mm	BMXP-3008	BMXP-3011	BMXP-3014	BMXP-3018	BMXP-3024	BMXP-3028	BMXP-3033	BMXP-3036
3,5 mm	BMXP-3508	BMXP-3511	BMXP-3514	BMXP-3518	BMXP-3524	BMXP-3528	BMXP-3533	BMXP-3536
4,0 mm	BMXP-4008	BMXP-4011	BMXP-4014	BMXP-4018	BMXP-4024	BMXP-4028		

Initial date: 16 May 2013
Revision date: 6 July 2016

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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

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ADDENDUM

Belonging to certificate: 2116857DE05

EC DESIGN-EXAMINATION
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):

LUMENO™ Flex - Drug Eluting Coronary Stent System

Stent lengths (mm) / Stent nominal diameters (mm)	8	11	14	18	24	28	33	36
2.25	LUFX2208	LUFX2211	LUFX2214	LUFX2218	LUFX2224	LUFX2228		
2.5	LUFX2508	LUFX2511	LUFX2514	LUFX2518	LUFX2524	LUFX2528	LUFX2533	LUFX2536
2.75	LUFX2708	LUFX2711	LUFX2714	LUFX2718	LUFX2724	LUFX2728	LUFX2733	LUFX2736
3.0	LUFX3008	LUFX3011	LUFX3014	LUFX3018	LUFX3024	LUFX3028	LUFX3033	LUFX3036
3.5	LUFX3508	LUFX3511	LUFX3514	LUFX3518	LUFX3524	LUFX3528	LUFX3533	LUFX3536
4.0	LUFX4008	LUFX4011	LUFX4014	LUFX4018	LUFX4024	LUFX4028		

Initial date: 6 July 2016

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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

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EC CERTIFICATE

Number: 2116857CE01

Full Quality Assurance System

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

Manufacturer:

Biosensors Europe SA

Rue de Lausanne 29
1110 Morges
Switzerland

For the product category(ies)

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 Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities 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 2022
Issued for the first time: 15 July 2008
Reissued: 17 July 2017
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: 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):

LUMENO™ Flex - Drug Eluting Coronary Stent System

Initial date: 6 July 2016

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

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 Flex™ - Drug Eluting Coronary Stent System

BioMatrix NeoFlex™ - Drug Eluting Coronary Stent System

Initial date: 15 July 2008
Revision date: 17 July 2017

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

BioMatrix DRUG ELUTING CORONARY STENT SYSTEM NeoFlex™

Raising the standard in deliverability

Ordering Information

	Stent Length (mm)							
Stent Diameter (mm)	**8**	**11**	**14**	**18**	**24**	**28**	**33**	**36**
2.25	BMXP-2208	BMXP-2211	BMXP-2214	BMXP-2218	BMXP-2224	BMXP-2228	NA	NA
2.50	BMXP-2508	BMXP-2511	BMXP-2514	BMXP-2518	BMXP-2524	BMXP-2528	BMXP-2533	BMXP-2536
2.75	BMXP-2708	BMXP-2711	BMXP-2714	BMXP-2718	BMXP-2724	BMXP-2728	BMXP-2733	BMXP-2736
3.00	BMXP-3008	BMXP-3011	BMXP-3014	BMXP-3018	BMXP-3024	BMXP-3028	BMXP-3033	BMXP-3036
3.50	BMXP-3508	BMXP-3511	BMXP-3514	BMXP-3518	BMXP-3524	BMXP-3528	BMXP-3533	BMXP-3536
4.00	BMXP-4008	BMXP-4011	BMXP-4014	BMXP-4018	BMXP-4024	BMXP-4028	NA	NA

* In vivo testing in porcine model demonstrates abluminal coating is absorbed after 6 to 9 months – Data on file at Biosensors International

1. LEADERS is a Biosensors International study. www.clinicaltrial.gov – NCT00389220
2. P. W. Serruys, LEADERS: 5-year follow-up from a prospective, randomized trial of Biolimus A9-eluting stents with a biodegradable polymer vs. sirolimus-eluting stents with a durable polymer, oral abstract presentation, TCT 2012
3. Data on file at Biosensors International

BioMatrix NeoFlex™ drug eluting stent system is CE approved.

Biosensors International Group, Ltd. licenses its proprietary BA9™ drug and PLA technology to Terumo Corporation (Nobori®).
The BioMatrix NeoFlex™ stent is indicated in diabetics, STEMI and ACS patients for stent lengths up to 28 mm.
LEADERS is a Biosensors International study. www.clinicaltrial.gov - NCT00389220.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Not available for sale in the United States and certain other countries.

www.**biosensors**.com

BIOSENSORS INTERNATIONAL™

BIOSENSORS EUROPE SA

Rue de Lausanne 29
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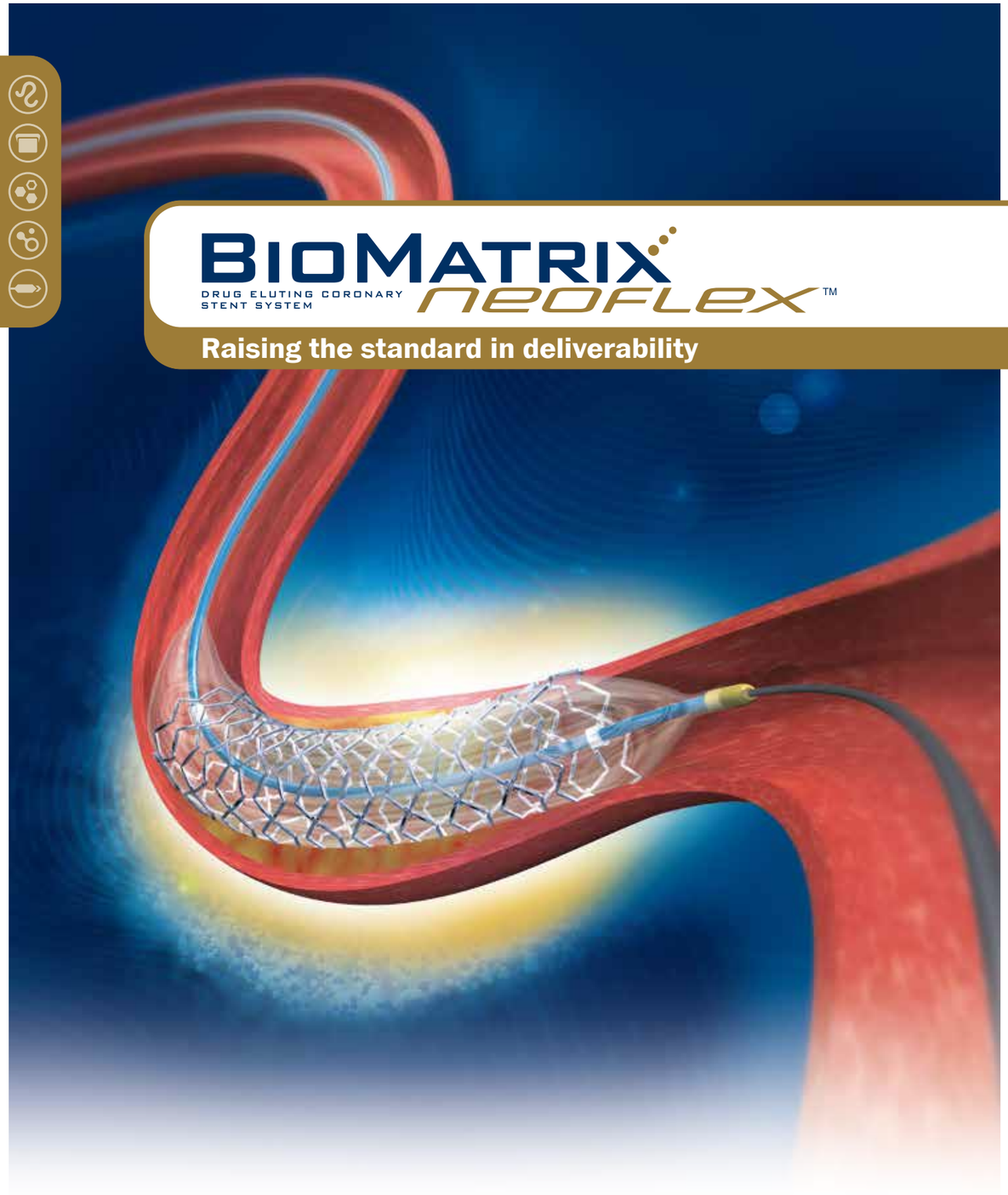


BioMatrix DRUG ELUTING CORONARY STENT SYSTEM NeoFlex™

Raising the standard in deliverability

BIOSENSORS INTERNATIONAL™

BioMatrix NeoFlex™: Exceptional performance – Premium deliverability

Biosensors brings you the newest member of the BioMatrix™ family:
BioMatrix NeoFlex.

With the LEADERS[1] trial 5-year results BioMatrix Flex™ achieved
Gold Standard status in biodegradable technology.

Now BioMatrix NeoFlex with an enhanced stent delivery system, brings
exceptional performance in complex lesions and challenging anatomy.

FLEX

BIOLIMUS A9™ DRUG

BIODEGRADABLE POLYMER

ABLUMINAL COATING

STENT PLATFORM

+

DELIVERY SYSTEM

NEW

Superior **trackability**

ADVANCED LOW PROFILE SDS

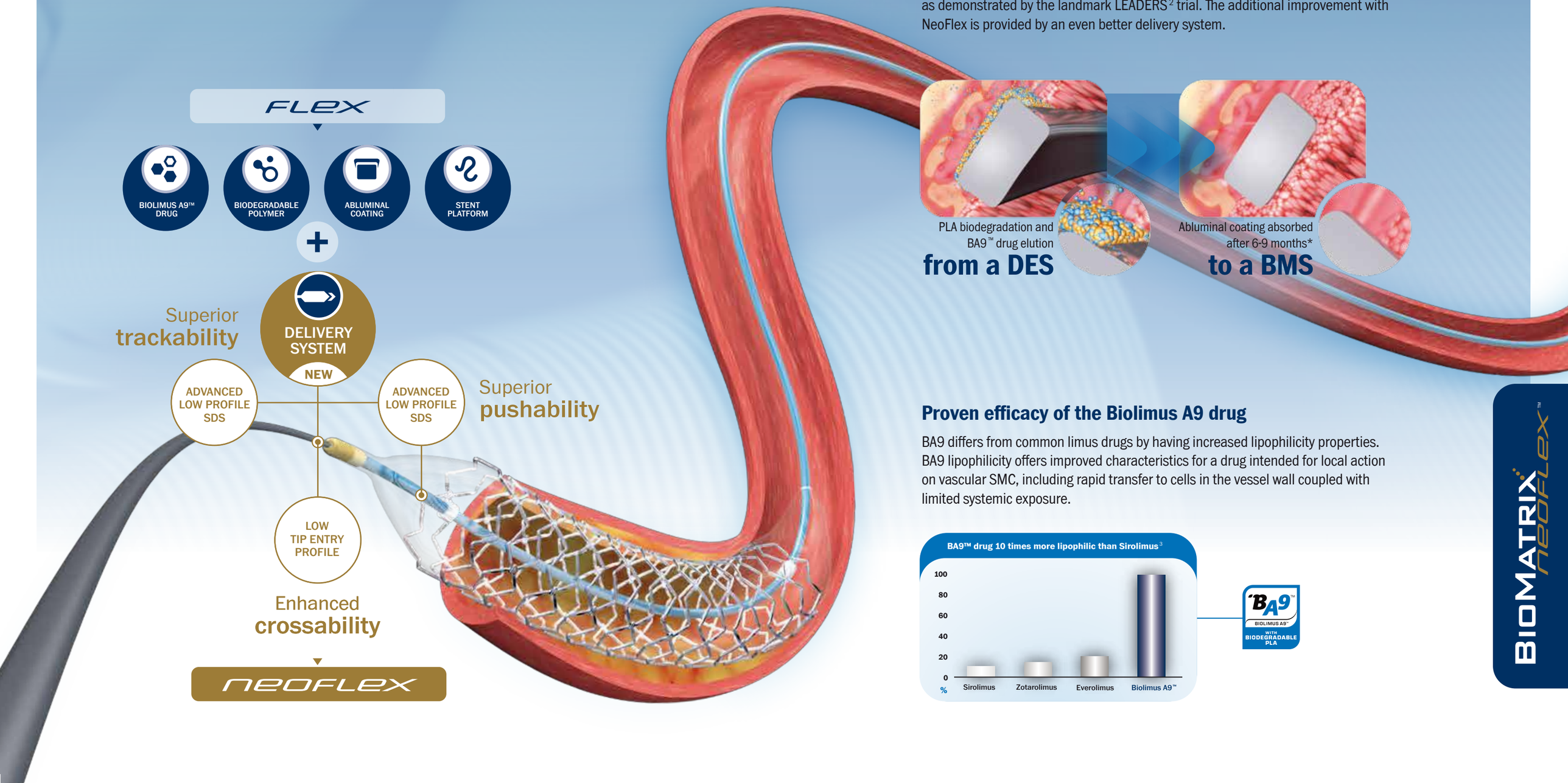
ADVANCED LOW PROFILE SDS

Superior **pushability**

LOW TIP ENTRY PROFILE

Enhanced **crossability**

NEOFLEX



BioMatrix NeoFlex: one step beyond

When it comes to biodegradable polymer technology, Biosensors has developed the highest level of expertise and delivered the best results in terms of safety and efficacy, as demonstrated by the landmark LEADERS[2] trial. The additional improvement with NeoFlex is provided by an even better delivery system.

Proven efficacy of the Biolimus A9 drug

BA9 differs from common limus drugs by having increased lipophilicity properties. BA9 lipophilicity offers improved characteristics for a drug intended for local action on vascular SMC, including rapid transfer to cells in the vessel wall coupled with limited systemic exposure.

BA9™ BIOLIMUS A9™ WITH BIODEGRADABLE PLA

BIOMATRIX NEOFLEX™

BioMatrix NeoFlex™

BIOSENSORS INTERNATIONAL™

TECHNICAL SPECIFICATIONS

DESCRIPTION:

The BioMatrix NeoFlex™ Drug Eluting Coronary Stent System (BioMatrix NeoFlex™ DES) is a Drug Eluting Stent (DES) System for coronary use with a biodegradable polymer coating. The DES is a combination product comprised of two key components: the stent, which includes the active BA9™ pharmaceutical ingredient (Biolimus A9™) incorporated into a polymer coating, and the delivery system.

COMPONENT DESCRIPTION:

- A balloon expandable intra-coronary 316L stainless steel stent with an abluminal biodegradable polymer coating containing BA9™ drug pre-mounted onto a semi-compliant rapid exchange balloon delivery system
- The delivery system has two radiopaque markers that fluoroscopically mark the ends of the stent to facilitate proper stent placement
- At the proximal end of the delivery system is a female luer lock connector hub which connects to the balloon inflation lumen
- The guidewire enters the distal tip of the catheter and exits 27.5 cm proximal to the tip of the delivery system.

COATING COMPONENT DESCRIPTION:

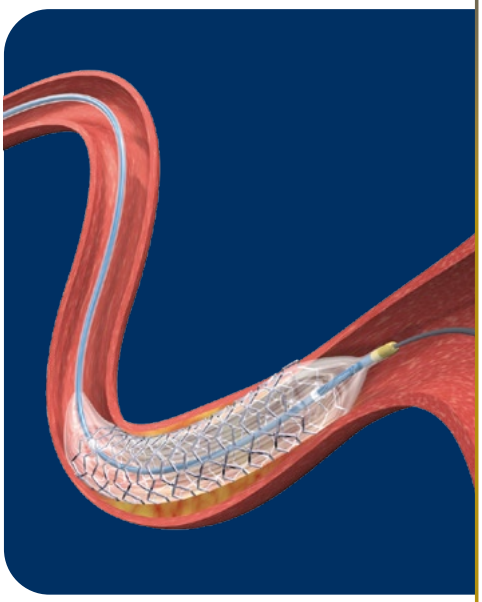
- BA9™, a proprietary formulation of umirolimus, is a semi-synthetic sirolimus derivative with enhanced pharmacokinetic properties
- BA9™ drug on the BioMatrix NeoFlex™ DES, inhibits muscle cell proliferation within the stent proximity
- Poly-lactic acid (PLA) acts as a carrier for the drug and biodegrades along with the drug elution.

INDICATIONS:

The BioMatrix NeoFlex™ abluminal biodegradable polymer DES is indicated for improving coronary luminal diameter and reducing stent restenosis for the treatment of *de novo* lesions in native coronary arteries with a reference diameter ranging from 2.25 mm and 4.00 mm (see “Instructions For Use” for more details). Stents with length 33 mm and 36 mm are only available for artery diameters ranging between 2.5 mm and 3.5 mm.
The BioMatrix NeoFlex™ DES with stent lengths up to 28 mm is also indicated for use in patients with **ST Elevated Myocardial Infarction** (STEMI), **Acute Coronary Syndromes** (ACS, including ACS-STEMI, ACS-NSTEMI and Unstable angina) and **Diabetes Mellitus**.

STENT DELIVERY SYSTEM:

Catheter design	Rapid Exchange	
Usable shaft length	142 cm	
Proximal shaft design	Hypotube	
Proximal shaft coating	Polyamide Jacket	
Proximal shaft profile	2.1 F / 0.0274" / 0.70 mm	
Shaft markers placement	90 and 100 cm from tip	
Distal shaft profile	3.0 mm	2.4 F/0.031”/0.79 mm (2.25-3.00 mm)
	4.0 mm	2.6 F/0.034”/0.86 mm (3.50-4.00 mm)
Lesion entry profile	0.016” based on bench test results*	
Balloon material	Polyamide Elastomer	
Balloon compliance	Semi-compliant	
Balloon folding	Tri-Fold	
Balloon cone	30 degrees	
Radiopaque markers	2 swaged platinum/iridium marker bands	
Length of balloon markers	0.5/0.9mm (distal/proximal)	
Nominal pressure	6 atm (608 kPa)	
Rated Burst Pressure	16 atm (1621 kPa) 2.25-3.00 mm	
	14 atm (1418 kPa) 3.50-4.00 mm	
Guiding catheter compatibility	5 F - 2.25 - 3.00 mm	
	6 F - 3.50 - 4.00 mm	
Guide wire compatibility	0.014"/ 0.36 mm	
Hydrophilic coating	W-II coating	



STENT PLATFORM:

Stent material	Stainless steel 316 L
Strut design	Corrugated rings
Link design	Quadrature Link™ (with "S" connector)
Strut thickness	0.0047" / 0.12 mm
Strut length	1.2 mm (6- and 9-crown model)
Stent crowns	6 crowns (2.25 mm-3.00 mm)
	9 crowns (3.50 mm-4.00 mm)
Stent crossing profile (max)	0.045" / 1.14 mm (3.0 mm, ≤ 28mm stent length)
Flexibility	Very good
Radiopacity	Good
Ferromagnetism	Non ferromagnetic (MRI safe)
Open cell diameter 6-crown model (3.0 mm)	1.56 mm
Foreshortening	≤ 10%
Elastic recoil	≤ 5%
Radial strength	> 0.67 bar / 500 mmHg

* Bench test data on file at Biosensors International (3.00mm x 18mm)

BioMatrix NeoFlex™

BIOSENSORS INTERNATIONAL™

TECHNICAL SPECIFICATIONS

DRUG:

Drug name	BA9™ (Biolimus A9™)
BA9™ drug dosage	15.6 µg/mm stent length

POLYMER:

PLA (Poly-Lactic Acid)	Biodegradable polymer

COATING:

Coating formulation	PLA/BA9™ drug
Nominal coating thickness	11 µm
Coating configuration	Abluminal

COMPLIANCE TABLE:

		Stent Internal Diameter (mm) by stent platform									
		For stent lengths from 8 to 28 mm						For stent lengths of 33 and 36 mm			
Pressure (atm)	6 Nominal Pressure (NP)	2.25	2.50	2.75	3.00	3.50	4.00	2.50	2.75	3.00	3.50
	7	2.28	2.53	2.78	3.03	3.53	4.03	2.53	2.78	3.04	3.55
	8	2.31	2.56	2.81	3.06	3.56	4.06	2.56	2.81	3.08	3.60
	9	2.34	2.59	2.84	3.09	3.59	4.09	2.59	2.84	3.12	3.65
	10	2.37	2.62	2.87	3.12	3.62	4.12	2.62	2.87	3.16	3.70
	11	2.40	2.65	2.90	3.15	3.65	4.15	2.65	2.90	3.20	3.75
	12	2.43	2.68	2.93	3.18	3.68	4.18	2.68	2.93	3.24	3.80
	13	2.46	2.71	2.96	3.21	3.71	4.21	2.71	2.96	3.28	3.85
	14 Rated Burst Pressure (RBP)	2.49	2.74	2.99	3.24	3.74	4.24	2.74	2.99	3.32	3.90
	15	2.52	2.77	3.02	3.27			2.77	3.02	3.36	
	16 Rated Burst Pressure (RBP)	2.55	2.80	3.05	3.30			2.80	3.05	3.40	

ORDERING INFORMATION:

	Stent Length (mm)							
Stent Diameter	8	11	14	18	24	28	33	36
2.25 mm	BMXP-2208	BMXP-2211	BMXP-2214	BMXP-2218	BMXP-2224	BMXP-2228		
2.50 mm	BMXP-2508	BMXP-2511	BMXP-2514	BMXP-2518	BMXP-2524	BMXP-2528	BMXP-2533	BMXP-2536
2.75 mm	BMXP-2708	BMXP-2711	BMXP-2714	BMXP-2718	BMXP-2724	BMXP-2728	BMXP-2733	BMXP-2736
3.00 mm	BMXP-3008	BMXP-3011	BMXP-3014	BMXP-3018	BMXP-3024	BMXP-3028	BMXP-3033	BMXP-3036
3.50 mm	BMXP-3508	BMXP-3511	BMXP-3514	BMXP-3518	BMXP-3524	BMXP-3528	BMXP-3533	BMXP-3536
4.00 mm	BMXP-4008	BMXP-4011	BMXP-4014	BMXP-4018	BMXP-4024	BMXP-4028		

Class III device, Rules 8, 13; MDD 93/42/EC

Single Use Product
Sterile unless package is open or damaged
Do not reuse or resterilize
The product is LATEX & PVC FREE

Sterilization method:	E-BEAM
CE certification:	DEKRA 0344
Shelf life:	12 months

Storage Conditions:

Store between 0°C and 25°C

For further information or assistance, please contact:

BIOSENSORS INTERNATIONAL

Legal Manufacturer – Sales and Customer Service:
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Fax +41 (0)21 804 80 01

www.biosensors.com

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