CARDIONOVUM®

Declaration of Conformity

Declaration No. 21/XL/01

according to the EN ISO/IEC 17050-1:2010

Manufacturer's name and address: CARDIONOVUM GmbH
Am Bonner Bogen 2
53227 Bonn, Germany

declares, that the below mentioned medical device:

Device Name: **XLIMUS Sirolimus Eluting Coronary Stent System**

Class; Rule: III; Rule 13

GMDN Code: 58771

Types/ Sizes:

Stent length (mm)	Stent diameter (mm)							
	2.25 mm	**2.50 mm**	**2.75 mm**	**3.00 mm**	**3.50 mm**	**4.00 mm**	**4.50 mm**	**5.00 mm**
8 mm	XL 2.25-8	XL 2.50-8	XL 2.75-8	XL 3.00-8	XL 3.50-8	XL 4.00-8	XL 4.50-8	XL 5.00-8
12 mm	XL 2.25-12	XL 2.50-12	XL 2.75-12	XL 3.00-12	XL 3.50-12	XL 4.00-12	XL 4.50-12	XL 5.00-12
16 mm	XL 2.25-16	XL 2.50-16	XL 2.75-16	XL 3.00-16	XL 3.50-16	XL 4.00-16	XL 4.50-16	XL 5.00-16
20 mm	XL 2.25-20	XL 2.50-20	XL 2.75-20	XL 3.00-20	XL 3.50-20	XL 4.00-20	XL 4.50-20	XL 5.00-20
24 mm	XL 2.25-24	XL 2.50-24	XL 2.75-24	XL 3.00-24	XL 3.50-24	XL 4.00-24	XL 4.50-24	XL 5.00-24
28 mm	XL 2.25-28	XL 2.50-28	XL 2.75-28	XL 3.00-28	XL 3.50-28	XL 4.00-28	XL 4.50-28	XL 5.00-28
32 mm	XL 2.25-32	XL 2.50-32	XL 2.75-32	XL 3.00-32	XL 3.50-32	XL 4.00-32	XL 4.50-32	XL 5.00-32
36 mm	XL 2.25-36	XL 2.50-36	XL 2.75-36	XL 3.00-36	XL 3.50-36	XL 4.00-36	XL 4.50-36	XL 5.00-36
40 mm	XL 2.25-40	XL 2.50-40	XL 2.75-40	XL 3.00-40	XL 3.50-40	XL 4.00-40	XL 4.50-40	XL 5.00-40

conforms to the following standards:

Standard:	**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 868-2:2017	Packaging for terminally sterilized medical devices. Sterilization wrap. Requirements and test methods.
EN 1041:2013	Information supplied by the manufacturer of medical devices
EN 1422:2014	Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods

according to the EN ISO/IEC 17050-1:2010

EN ISO 10555-1:2013/ Amd 1:2017	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements
EN ISO 10555-4:2013	Intravascular catheters - Sterile and single-use catheters Part 4: Balloon dilatation catheters
EN ISO 10993-1:2018	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 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2016	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
EN ISO 10993-7:2008/ Amd 1:2019	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10:2013	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2017	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
EN ISO 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of materials
EN ISO 11135:2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11138-1:2017	Sterilization of health care products — Biological indicators — Part 1: General requirements
EN ISO 11138-2:2017	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018	Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products
EN ISO 12417-1:2015	Cardiovascular extracorporeal systems – Vascular device-drug combination products – Part 1: General requirements
EN ISO 13408-1:2018/ Amd 1:2013	Aseptic processing of health care products — Part 1: General requirements

according to the EN ISO/IEC 17050-1:2010

EN ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects — Good clinical practice
EN ISO 14630:2012	Non-active surgical implants — General requirements
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
EN ISO 14644-3:2019	Cleanrooms and associated controlled environments — Part 3: Test methods
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments -Biocontamination control - Part 1: General principles and methods
EN ISO 14698-2:2003	Cleanrooms and associated controlled environments -Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
EN ISO 14971:2019	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 ISO/IEC 17050-1:2010	Conformity assessment -- Supplier's declaration of conformity -- 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
Ph.Eur. current edition, <General Methods, 2.6.1>	Sterility
Ph.Eur. current edition, <General Methods, 2.6.14>	Bacterial Endotoxins (LAL)
ISTA 2A	Packaged-Products weighing 150 lb (68 kg) or Less
ASTM F1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1886/ F1886M - 09	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F88 / F88M - 09	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1929 – 15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096 – 11	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

according to the EN ISO/IEC 17050-1:2010

Supplementary Information:

The device herewith complies with the requirements of the:

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993concerning medical devices, Annex II including section 4;
- DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

In addition, the device is covered by the certificates and carries the CE-marking accordingly:

- Full Quality Assurance System EC Certificate reference number **1434-MDD-151/2021** issued on **26.03.2021** by PCBC S.A., Pulawska 469 St., PL02-844 Warsaw; Poland, Notified Body Identification Number 1434
- EC Design – Examination Certificate reference number **1434-MDD-150/2021** issued on **26.03.2021** by PCBC S.A., Pulawska 469 St., PL02-844 Warsaw; Poland, Notified Body Identification Number 1434;
- Certificate of Management System according to the PN-EN ISO 13485:2016 standard, reference number **M-62/1/2018** issued on **11.12.2018** by PCBC S.A., Pulawska 469 St., PL02-844 Warsaw; Poland, Certification Body.

CE 1434

CARDIONOVUM GmbH
Am Bonner Bogen 2
53227 Bonn
Tel +49 228 909059-0
www.cardionovum.com

Bonn, 07.04.2021 **by: Jolanthe MENDT, Quality & Regulatory Affairs Director**

For regulatory topics only, contact:

CARDIONOVUM GmbH
Am Bonner Bogen 2
53227 Bonn, Germany
Jolanthe Mendt, Quality & Regulatory Affairs Director
quality@cardionovum.com
Phone: +49 228 90 90 59-0
Fax: +49 228 90 90 59-20

CERTIFICATE

No. M - 62/1/2018

This is to certify that:

CARDIONOVUM GmbH

Am Bonner Bogen 2, 53227 Bonn, Germany

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

design, development, manufacturing, final control, sales and distribution of sterile, non-active endovascular and cardiovascular medical devices for interventional applications, coated with medicinal substances and uncoated

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 11.12.2018 to 10.12.2021

PARTNER OF IQNet

AC 019
QMS

Anna Wyroba, M.Sc.
Vice President

Certificate No. **M - 62/1/2018**
Issued under the Contract No. 3660/M/2018
Date of certification decision: 22.11.2018
Bears the PCBC hologram.
Warsaw, 22.11.2018

CARDIONOVUM®

Declaration of Conformity

Declaration No. 19/R/01

according to the EN ISO/IEC 17050-1:2010

Manufacturer's name and address: CARDIONOVUM GmbH
Am Bonner Bogen 2
53227 Bonn, Germany

declares, that the below mentioned medical device:

Device Name: **RESTORE DEB Paclitaxel Releasing PTCA Balloon Catheter**

Class; Rule: III; Rule 6 and 13

Types/ Sizes:

conforms to the following standards:

		Balloon diameter (mm)						
		2.00	**2.25**	**2.50**	**2.75**	**3.00**	**3.50**	**4.00**
Balloon length (mm)	**15**	R 2.00-15	R 2.25-15	R 2.50-15	R 2.75-15	R 3.00-15	R 3.50-15	R 4.00-15
	20	R 2.00-20	R 2.25-20	R 2.50-20	R 2.75-20	R 3.00-20	R 3.50-20	R 4.00-20
	25	R 2.00-25	R 2.25-25	R 2.50-25	R 2.75-25	R 3.00-25	R 3.50-25	R 4.00-25
	30	R 2.00-30	R 2.25-30	R 2.50-30	R 2.75-30	R 3.00-30	R 3.50-30	R 4.00-30

Standard:	**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 868-2:2017	Packaging for terminally sterilized medical devices. Sterilization wrap. Requirements and test methods.
EN 1041:2013	Information supplied by the manufacturer of medical devices
EN 1422:2014	Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods
EN ISO 10555-1:2013	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements
EN ISO 10555-4:2013	Intravascular catheters - Sterile and single-use catheters Part 4: Balloon dilatation catheters
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 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2016	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
EN ISO 10993-7:2008	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals

Declaration No. 19/R/01

according to the EN ISO/IEC 17050-1:2010

Standard:	Title:
EN ISO 10993-10:2013	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
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
EN ISO 10993-18:2009	Biological evaluation of medical devices — Part 18: Chemical characterization of materials
EN ISO 11135:2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11138-1:2017	Sterilization of health care products — Biological indicators — Part 1: General requirements
EN ISO 11138-2:2017	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1:2009 /A1:2014-09	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006/A1:2014	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 12417-1:2015	Cardiovascular extracorporeal systems – Vascular device-drug combination products – Part 1: General requirements
EN ISO 13408-1:2015	Aseptic processing of health care products — Part 1: General requirements
PN EN ISO 13485:2016/AC:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects — Good clinical practice
EN ISO 14630:2012	Non-active surgical implants — General requirements
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
EN ISO 14644-3:2005	Cleanrooms and associated controlled environments — Part 3: Test methods
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments -Biocontamination control - Part 1: General principles and methods
EN ISO 14698-2:2003	Cleanrooms and associated controlled environments -Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
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 ISO/IEC 17050-1:2010	Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements
Ph.Eur. current edition,<1794>	Paclitaxel
Ph.Eur. current edition,<1149>	Shellac
ISTA 2A	Packaged-Products weighing 150 lb (68 kg) or Less
ASTM F1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1886/ F1886M - 09	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F88 / F88M - 09	Standard Test Method for Seal Strength of Flexible Barrier Materials

CARDIONOVUM®

Declaration of Conformity

Declaration No. 19/R/01

according to the EN ISO/IEC 17050-1:2010

Standard:	Title:
ASTM F1929 – 15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096 – 11	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

Supplementary Information:

The device herewith complies with the requirements of the:

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993concerning medical devices, Annex II including section 4;
- DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

In addition, the device is covered by the certificates and carries the CE-marking accordingly:

- Full Quality Assurance System EC Certificate reference number 1434-MDD-333/2019 issued on 31.05.2019 by PCBC S.A., Klobucka 23A St., PL02-699 Warsaw; Poland, Notified Body Identification Number 1434
- EC Design – Examination Certificate reference number 1434-MDD-332/2019 issued on 31.05.2019, by PCBC S.A., Klobucka 23A St., PL02-699 Warsaw; Poland, Notified Body Identification Number 1434;
- Certificate of Management System according to the PN-EN ISO 13485:2016 standard, reference number M-62/1/2018 issued on 11.12.2018 by PCBC S.A., Klobucka 23A St., PL02-699 Warsaw; Poland, Certification Body.

CE
1434

CARDIONOVUM GmbH
Am Bonner Bogen 2
D-53227 Bonn
Tel.: +49 - 228 / 90 90 59 0
E-Mail: info@cardionovum.com

Bonn: date 11.06.2019

by: Jolanthe Mendt
Quality & Regulatory Affairs Director

For regulatory topics only, contact:

Cardionovum GmbH
Am Bonner Bogen 2
53227 Bonn, Germany
JOLANTHE MENDT
jolanthe.mendt@cardionovum.com
Ph: +49 228 9090590
Fax: +49 228 909059-20

CERTIFICATE

EC No 1434-MDD-332/2019
EC Design-Examination

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

CARDIONOVUM GmbH

Am Bonner Bogen 2
53227 Bonn, Germany

related to the medical device
class III

RESTORE DEB Paclitaxel Releasing PTCA Balloon Catheter

The list of medical devices covered by this certificate is given in the Annex no. 1

complies with requirements of Annex II p. 4 to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 31.05.2019 to 30.05.2024

The date of issue of the Certificate: 31.05.2019

CE 1434

mgr Anna Wyroba
Vice-President

Application No: 251/2018
Module: H1

Certificate No. **1434-MDD-332/2019**
Issued under the Contract No MD-02/2019
Bears the PCBC hologram.
Warsaw, 31.05.2019

ANNEX no. 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-332/2019

The products detailed below are covered under the scope of this certificate:

		Balloon diameter (mm)						
		2.00	2.25	2.50	2.75	3.00	3.50	4.00
Balloon length (mm)	15	R 2.00-15	R 2.25-15	R 2.50-15	R 2.75-15	R 3.00-15	R 3.50-15	R 4.00-15
	20	R 2.00-20	R 2.25-20	R 2.50-20	R 2.75-20	R 3.00-20	R 3.50-20	R 4.00-20
	25	R 2.00-25	R 2.25-25	R 2.50-25	R 2.75-25	R 3.00-25	R 3.50-25	R 4.00-25
	30	R 2.00-30	R 2.25-30	R 2.50-30	R 2.75-30	R 3.00-30	R 3.50-30	R 4.00-30

CE 1434

mgr Anna Wyroba
Vice-President

Annex 1 to certificate No. **1434-MDD-332/2019**
Issued under the Contract No. MD-02/2019
Bears the PCBC hologram.
Warsaw, 31.05.2019

CERTIFICATE

EC No 1434-MDD-333/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

CARDIONOVUM GmbH

Am Bonner Bogen 2
53227 Bonn, Germany

for the design, manufacture and final inspection of medical device
class III

RESTORE DEB Paclitaxel Releasing PTCA Balloon Catheter

List of devices covered by this certificate is given in the Annex no. 1

was examined in accordance with Annex II excluding p. 4 to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 31.05.2019 to 30.05.2024

The date of issue of the Certificate: 31.05.2019

CE 1434

mgr Anna Wyroba
Vice-President

Application No: 251/2018
Module: H2

Certificate No. **1434-MDD-333/2019**
Issued under the Contract No MD-02/2019
Bears the PCBC hologram.
Warsaw, 31.05.2019

ANNEX no. 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-333/2019

The products detailed below are covered under the scope of this certificate:

		Balloon diameter (mm)						
		2.00	2.25	2.50	2.75	3.00	3.50	4.00
Balloon length (mm)	15	R 2.00-15	R 2.25-15	R 2.50-15	R 2.75-15	R 3.00-15	R 3.50-15	R 4.00-15
	20	R 2.00-20	R 2.25-20	R 2.50-20	R 2.75-20	R 3.00-20	R 3.50-20	R 4.00-20
	25	R 2.00-25	R 2.25-25	R 2.50-25	R 2.75-25	R 3.00-25	R 3.50-25	R 4.00-25
	30	R 2.00-30	R 2.25-30	R 2.50-30	R 2.75-30	R 3.00-30	R 3.50-30	R 4.00-30

CE 1434

mgr Anna Wyroba
Vice-President

Annex 1 to certificate No. **1434-MDD-333/2019**
Issued under the Contract No. MD-02/2019
Bears the PCBC hologram.
Warsaw, 31.05.2019

Declaration of Conformity

CARDIONOVUM®
Life deserves the best

Declaration No. 18/XL/03

according to the EN ISO/IEC 17050-1:2010

Manufacturer's name and address: CARDIONOVUM GmbH
Am Bonner Bogen 2
53227 Bonn, Germany

declares, that the below mentioned medical device:

Device Name: **XLIMUS Sirolimus Eluting Coronary Stent System**

Class; Rule: III; Rule 8 and 13

Types/ Sizes:

Stent ength (mm)	Stent diameter (mm)							
	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.50 mm	4.00 mm	4.50 mm	5.00 mm
8 mm	XL 2.25-8	XL 2.50-8	XL 2.75-8	XL 3.00-8	XL 3.50-8	XL 4.00-8	XL 4.50-8	XL 5.00-8
12mm	XL 2.25-12	XL 2.50-12	XL 2.75-12	XL 3.00-12	XL 3.50-12	XL 4.00-12	XL 4.50-12	XL 5.00-12
16 mm	XL 2.25-16	XL 2.50-16	XL 2.75-16	XL 3.00-16	XL 3.50-16	XL 4.00-16	XL 4.50-16	XL 5.00-16
20 mm	XL 2.25-20	XL 2.50-20	XL 2.75-20	XL 3.00-20	XL 3.50-20	XL 4.00-20	XL 4.50-20	XL 5.00-20
24 mm	XL 2.25-24	XL 2.50-24	XL 2.75-24	XL 3.00-24	XL 3.50-24	XL 4.00-24	XL 4.50-24	XL 5.00-24
28 mm	XL 2.25-28	XL 2.50-28	XL 2.75-28	XL 3.00-28	XL 3.50-28	XL 4.00-28	XL 4.50-28	XL 5.00-28
32 mm	XL 2.25-32	XL 2.50-32	XL 2.75-32	XL 3.00-32	XL 3.50-32	XL 4.00-32	XL 4.50-32	XL 5.00-32
36 mm	XL 2.25-36	XL 2.50-36	XL 2.75-36	XL 3.00-36	XL 3.50-36	XL 4.00-36	XL 4.50-36	XL 5.00-36
40 mm	XL 2.25-40	XL 2.50-40	XL 2.75-40	XL 3.00-40	XL 3.50-40	XL 4.00-40	XL 4.50-40	XL 5.00-40

conforms to the following standards:

Standard:	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 868-2:2017	Packaging for terminally sterilized medical devices. Sterilization wrap. Requirements and test methods.
EN 1041:2013	Information supplied by the manufacturer of medical devices
EN 1422:2014	Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods
EN ISO 10555-1:2013	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements
EN ISO 10555-4:2013	Intravascular catheters - Sterile and single-use catheters Part 4: Balloon dilatation catheters

according to the EN ISO/IEC 17050-1:2010

Standard:	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 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2016	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
EN ISO 10993-7:2008	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10:2013	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
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
EN ISO 10993-18:2009	Biological evaluation of medical devices — Part 18: Chemical characterization of materials
EN ISO 11135:2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11138-1:2017	Sterilization of health care products — Biological indicators — Part 1: General requirements
EN ISO 11138-2:2017	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1:2009 /A1:2014-09	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006/A1:2014	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 12417-1:2015	Cardiovascular extracorporeal systems – Vascular device-drug combination products – Part 1: General requirements
EN ISO 13408-1:2015	Aseptic processing of health care products — Part 1: General requirements
PN EN ISO 13485:2012/AC:2012	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects — Good clinical practice
EN ISO 14630:2012	Non-active surgical implants — General requirements
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
EN ISO 14644-3:2005	Cleanrooms and associated controlled environments — Part 3: Test methods
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments -Biocontamination control - Part 1: General principles and methods
EN ISO 14698-2:2003	Cleanrooms and associated controlled environments -Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
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 ISO/IEC 17050-1:2010	Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements
EN ISO 25539-2012	Cardiovascular implants. Endovascular devices. Part 2: Vascular stents

according to the EN ISO/IEC 17050-1:2010

Standard:	Title:
ISTA 2A	Packaged-Products weighing 150 lb (68 kg) or Less
ASTM F1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1886/ F1886M - 09	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F88 / F88M - 09	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1929 – 15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096 – 11	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

Supplementary Information:

The device herewith complies with the requirements of the:

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993concerning medical devices, Annex II including section 4;
- DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

In addition, the device is covered by the certificates and carries the CE-marking accordingly:

- Full Quality Assurance System EC Certificate reference number **1434-MDD-134/2018** issued on **11.12.2018** by PCBC S.A., Klobucka 23A St., PL02-699 Warsaw; Poland, Notified Body Identification Number 1434
- EC Design – Examination Certificate reference number **1434-MDD-133/2018** issued on **11.12.2018** by PCBC S.A., Klobucka 23A St., PL02-699 Warsaw; Poland, Notified Body Identification Number 1434;
- Certificate of Management System according to the PN-EN ISO 13485:2012 standard, reference number M-62/1/2018 issued on 11.12.2018 by PCBC S.A., Klobucka 23A St., PL 02-699 Warsaw; Poland, Certification Body.

CE
1434

Bonn, 05.02.2019 **by: Andrew Traver, CTO**

CARDIONOVUM GmbH
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CERTIFICATE

EC No 1434-MDD-133/2018
EC Design-Examination

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

CARDIONOVUM GmbH

Am Bonner Bogen 2
53227 Bonn, Germany

related to the medical device
class III

XLIMUS Sirolimus Eluting Coronary Stent System

The list of medical devices covered by this certificate is given in the Annex no. 1

complies with requirements

of Annex II p. 4 to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 11.12.2018 to 27.03.2021

The date of issue of the Certificate: 11.12.2018

The date of the first issue of the Certificate: 28.03.2013

CE 1434

mgr Anna Wyroba
Vice-President

Application No: 196/2017
Module: H1

Certificate No **1434-MDD-133/2018**
Issued under the Contract No MD-01/2018
Bears the PCBC hologram.
Warsaw, 11.12.2018

ANNEX no. 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No. 1434-MDD-133/2018

The list of medical devices covered by the certificate

Stent Length (mm)	Stent Diameter (mm)							
	2.25	2.50	2.75	3.00	3.50	4.00	4.50	5.00
8	XL 2.25-8	XL 2.50-8	XL 2.75-8	XL 3.00-8	XL 3.50-8	XL 4.00-8	XL 4.50-8	XL 5.00-8
12	XL 2.25-12	XL 2.50-12	XL 2.75-12	XL 3.00-12	XL 3.50-12	XL 4.00-12	XL 4.50-12	XL 5.00-12
16	XL 2.25-16	XL 2.50-16	XL2.75-16	XL 3.00-16	XL 3.50-16	XL 4.00-16	XL4.50-16	XL 5.00-16
20	XL 2.25-20	XL 2.50-20	XL 2.75-20	XL 3.00-20	XL 3.50-20	XL 4.00-20	XL 4.50-20	XL 5.00-20
24	XL 2.25-24	XL 2.50-24	XL 2.75-24	XL 3.00-24	XL 3.50-24	XL 4.00-24	XL 4.50-24	XL 5.00-24
28	XL 2.25-28	XL 2.50-28	XL 2.75-28	XL 3.00-28	XL3.50-28	XL 4.00-28	XL4.50-28	XL 5.00-28
32	XL2.25-32	XL 2.50-32	XL 2.75-32	XL 3.00-32	XL3.50-32	XL 4.00-32	XL 4.50-32	XL 5.00-32
36	XL 2.25-36	XL 2.50-36	XL 2.75-36	XL 3.00-36	XL3.50-36	XL4.00-36	XL 4.50-36	XL 5.00-36
40	XL 2.25-40	XL 2.50-40	XL 2.75-40	XL 3.00-40	XL 3.50-40	XL 4.00-40	XL 4.50-40	XL 5.00-40

CE 1434

mgr Anna Wyroba
Vice-President

Annex to certificate No. **1434-MDD-133/2018**
Issued under the Contract No MD-01/2018
Bears the PCBC hologram.
Warsaw, 11.12.2018

CERTIFICATE

EC No 1434-MDD-134/2018
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies,
that the quality assurance system in the organization:

CARDIONOVUM GmbH

Am Bonner Bogen 2
53227 Bonn, Germany

for the design, manufacture and final inspection of medical device
class III

XLIMUS Sirolimus Eluting Coronary Stent System

was examined in accordance

with Annex II excluding p. 4 to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 11.12.2018 to 27.03.2021

The date of issue of the Certificate: 11.12.2018

The date of the first issue of the Certificate: 28.03.2013

CE 1434

mgr Anna Wyroba
Vice-President

Application No: 196/2017
Module: H2

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

Certificate No **1434-MDD-134/2018**
Issued under the Contract No MD-01/2018
Bears the PCBC hologram.
Warsaw, 11.12.2018