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

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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

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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

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Bonn: date 11.06.2019

by: Jolanthe Mendt
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