



# 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



Application No: 251/2018  
Module: H1

  
mgr Anna Wyroba  
Vice-President



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



*Anna Wyroba*  
mgr Anna Wyroba  
Vice-President



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