

**We****Manufacturer's name** **CARDIONOVUM GmbH****address:** Am Bonner Bogen 2  
53227 Bonn, Germany  
**SRN** DE-MF-000005316

**hereby declare on our sole responsibility that the below mentioned medical device:**

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

**Class; Rule:** III; Rule 13

**EMDN code** C0104010201

**GMDN Code:** 62218

**UMDNS code** 17184

**Basic UDI** 590619015RESTOREW9

**Types/ Sizes:**

Balloon length (mm)	Balloon diameter (mm)						
	2.00	2.25	2.50	2.75	3.00	3.50	4.00
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

**complies with the requirements of the:**

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning 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.

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**Supplementary information**

<b>Notified body involved in assessment procedure</b>	Polish Centre for Testing and Certification S.A.	<b>NB Identification number</b>	1434
<b>Address:</b>	Pulawska 469 St., 02-844 Warsaw; Poland		
<b>Conformity assessment procedure:</b>	Annex II including section 4		
<b>EC Certificate:</b>	1434-MDD-332/2019	EC-Design Examination	
<b>EC Certificate</b>	1434-MDD-333/2019	Full Quality Assurance System	

Manufacturer established Quality Management System and obtain Certificate of Management System according to the EN ISO 13485:2016 standard, reference number M-62/2/2021 valid from 11.12.2021 issued by PCBC S.A., Pulawska 469 St., PL 02-844 Warsaw; Poland, Certification Body

Additionally, the aforementioned device meets provisions of the standards incl. harmonised standards set in **Annex I** to this Declaration.

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**For regulatory topics only, contact:**

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**Bonn, date next to signature**

**Declaration bears as qualified signature**

**by: Monika MROCZKIEWICZ, Quality & Regulatory Affairs Director**