CARDIONOVUM
Life deserves the best

LOA-0758

Bonn, September 20th, 2023.

Authorization

We, the undersigned Cardionovum GmbH, Am Bonner Bogen 2, 53227 Bonn, Germany, herby appoint “AG Medical” S.R.L., 17/6, N. Testimiteanu street, MD-2025, Chisinau, Republic of Moldova, to be authorized distributor/ representative for registration, renewal, amendments of registration, at the responsible authorities of the Republic of Moldova.

This Authorization is valid until December 31st, 2024.

Miquel Craven-Bartle
CEO

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

Digitally signed by Rusu Cristina
Date: 2023.10.13 14:53:46 EEST
Reason: MoldSign Signature
Location: Moldova

CARDIONOVUM GmbH
Am Bonner Bogen 2
53227 Bonn, Germany
Phone: +49 (0) 228 / 90 90 59 – 0
Fax: +49 (0) 228 / 90 90 59 - 20

Geschäftsführer
Miquel Craven-Bartle Capella, (CEO)

Registergericht Bonn
Bonn HRB 14153
info@cardionovum.com
www.cardionovum.com

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul ***"AG Medical" S.R.L.****, cu sediul în* ***mun. Chișinău, str. N.Testemitanu 17/6****, tel:* ***068864448****, e-mail:* sc.agmedical.srl@gmail.com,

declar pe proprie răspundere, cunoscând prevederile art. ***352[1]*** *, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:*

1)RESTORE® DEB
Paclitaxel Releasing PTCA Balloon Catheter::

R 2.00-15	*R 2.00-20*	*R 2.00-25*	*R 2.00-30*
R 2.25-15	*R 2.25-20*	*R 2.25-25*	*R 2.25-30*
R 2.50-15	*R 2.50-20*	*R 2.50-25*	*R 2.50-30*
R 2.75-15	*R 2.75-20*	*R 2.75-25*	*R 2.75-30*
R 3.00-15	*R 3.00-20*	*R 3.00-25*	*R 3.00-30*
R 3.50-15	*R 3.50-20*	*R 3.50-25*	*R 3.50-30*
R 4.00-15	*R 4.00-20*	*R 4.00-25*	*R 4.00-30*

Sunt autentice și corespund realității

Cristina Rusu, administrator *Semnătura* _____

13.10.2023

Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 4 din 13.10.2023

Solicitantul "AG Medical" S.R.L., cu sediul în mun. Chișinău, str. N.Testemitanu 17/6, tel: 068864448, e-mail: sc.agmedical.srl@gmail.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1) RESTORE® DEB
Paclitaxel Releasing PTCA Balloon Catheter:

R 2.00-15	R 2.75-20	R 4.00-25
R 2.25-15	R 3.00-20	
R 2.50-15	R 3.50-20	R 2.00-30
R 2.75-15	R 4.00-20	R 2.25-30
R 3.00-15		R 2.50-30
R 3.50-15	R 2.00-25	R 2.75-30
R 4.00-15	R 2.25-25	R 3.00-30
	R 2.50-25	R 3.50-30
R 2.00-20	R 2.75-25	R 4.00-30
R 2.25-20	R 3.00-25	
R 2.50-20	R 3.50-25	

Se anexează următoarele acte:

1. Declarații de Conformitate CE
2. Certificatul de Conformitate CE
3. Actul prin care producătorul își desemnează reprezentantul
4. Declarație pe propria răspundere.

Cristina Rusu
13.10.2023

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

CARDIONOVUM
Life deserves the best

Declaration of Conformity

Declaration No. 22/R/01

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 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.

Declaration of Conformity

Declaration No. 22/R/01

Supplementary information

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

For regulatory topics only, contact:

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

CE
1434

Bonn, date next to signature

Digitally signed by Monika Mroczkiewicz
Date: 2023.04.25 14:21:14 +02'00'

Declaration bears as qualified signature

by: Monika MROCZKIEWICZ, Quality & Regulatory Affairs Director

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