

Bonn, September 20th, 2023.

Authorization

We, the undersigned Cardionovum GmbH, Am Bonner Bogen 2, 53227 Bonn, Germany, hereby 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

Către
Agenția Medicamentului
și 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. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1)LEGFLOW® RX

Paclitaxel Releasing Peripheral Balloon Dilatation Catheter:

L2.0-20 RX	L2.5-40 RX	L3.0-60 RX	L3.5-80 RX
L2.0-40 RX	L2.5-60 RX	L3.0-80 RX	L3.5-100 RX
L2.0-60 RX	L2.5-80 RX	L3.0-100 RX	L3.5-120 RX
L2.0-80 RX	L2.5-100 RX	L3.0-120 RX	L3.5-150 RX
L2.0-100 RX	L2.5-120 RX	L3.0-150 RX	
L2.0-120 RX	L2.5-150 RX	L3.0-200 RX	L4.0-20 RX
L2.0-150 RX	L2.5-200 RX		L4.0-40 RX
L2.0-200 RX		L3.5-20 RX	L4.0-80 RX
	L3.0-20 RX	L3.5-40 RX	L4.0-120RX
L2.5-20 RX	L3.0-40 RX	L3.5-60 RX	

2)LEGFLOW® OTW

Paclitaxel Releasing Peripheral Balloon Dilatation Catheter:

LegflowOTW 0.035"	LS 4.0-120 OTW L 4.0-120 OTW	L 5.0-80 OTW LS 5.0-100 OTW	LS 6.0-60 OTW L 6.0-60 OTW
LS 4.0-20 OTW L 4.0-20 OTW	LS 4.0-150 OTW L 4.0-150 OTW	L 5.0-100 OTW LS 5.0-120 OTW	LS 6.0-80 OTW L 6.0-80 OTW
LS 4.0-40 OTW L 4.0-40 OTW	LS 5.0-20 OTW L 5.0-20 OTW	L 5.0-120 OTW LS 5.0-150 OTW	LS 6.0-100 OTW L 6.0-100 OTW
LS 4.0-60 OTW L 4.0-60 OTW	LS 5.0-40 OTW L 5.0-40 OTW	L 5.0-150 OTW LS 6.0-20 OTW	LS 6.0-120 OTW L 6.0-120 OTW
LS 4.0-80 OTW L 4.0-80 OTW	LS 5.0-60 OTW L 5.0-60 OTW	LS 6.0-20 OTW L 6.0-20 OTW	LS 6.0-150 OTW L 6.0-150 OTW
LS 4.0-100 OTW L 4.0-100 OTW	LS 5.0-80 OTW L 5.0-80 OTW	LS 6.0-40 OTW L 6.0-40 OTW	LS 7.0-20 OTW

L 7.0-20 OTW
LS 7.0-40 OTW
L 7.0-40 OTW
LS 7.0-60 OTW
L 7.0-60 OTW
LS 7.0-80 OTW
L 7.0-80 OTW
LS 7.0-100 OTW
L 7.0-100 OTW
LS 7.0-120 OTW
L 7.0-120 OTW
LS 7.0-150 OTW
L 7.0-150 OTW

LS 8.0-20 OTW
L 8.0-20 OTW

LS 8.0-40 OTW
L 8.0-40 OTW
LS 8.0-60 OTW
L 8.0-60 OTW
LS 8.0-80 OTW
L 8.0-80 OTW
LS 8.0-100 OTW
L 8.0-100 OTW
LS 8.0-120 OTW
L 8.0-120 OTW
LS 8.0-150 OTW
L 8.0-150 OTW

LS 9.0-20 OTW
L 9.0-20 OTW
LS 9.0-40 OTW

L 9.0-40 OTW
LS 9.0-60 OTW
L 9.0-60 OTW

LS 10.0-20 OTW
L 10.0-20 OTW
LS 10.0-40 OTW
L 10.0-40 OTW
LS 10.0-60 OTW
L 10.0-60 OTW

Legflow OTW 0.014''
L 2.0-40 OTW
L 2.0-80 OTW
L 2.0-120 OTW

L 2.0-150 OTW
L 2.5-40 OTW
L 2.5-80 OTW
L 2.5-120 OTW
L 2.5-150 OTW
L 3.0-40 OTW
L 3.0-80 OTW
L 3.0-120 OTW
L 3.0-150 OTW
L 3.5-40 OTW
L 3.5-80 OTW
L 3.5-120 OTW
L 3.5-150 OTW

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 Agenția Medicamentului
și Dispozitivelor Medicale

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

nr. 3 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 și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1) LEGFLOW® RX

Paclitaxel Releasing Peripheral Balloon Dilatation Catheter:

L2.0-20 RX	L2.5-100 RX	
L2.0-40 RX	L2.5-120 RX	L3.5-20 RX
L2.0-60 RX	L2.5-150 RX	L3.5-40 RX
L2.0-80 RX	L2.5-200 RX	L3.5-60 RX
L2.0-100 RX		L3.5-80 RX
L2.0-120 RX	L3.0-20 RX	L3.5-100 RX
L2.0-150 RX	L3.0-40 RX	L3.5-120 RX
L2.0-200 RX	L3.0-60 RX	L3.5-150 RX
	L3.0-80 RX	
L2.5-20 RX	L3.0-100 RX	L4.0-20 RX
L2.5-40 RX	L3.0-120 RX	L4.0-40 RX
L2.5-60 RX	L3.0-150 RX	L4.0-80 RX
L2.5-80 RX	L3.0-200 RX	L4.0-120 RX

2) LEGFLOW® OTW

Paclitaxel Releasing Peripheral Balloon Dilatation Catheter:

Legflow OTW 0.035''	L 4.0-80 OTW	LS 5.0-20 OTW
LS 4.0-20 OTW	LS 4.0-100 OTW	L 5.0-20 OTW
L 4.0-20 OTW	L 4.0-100 OTW	LS 5.0-40 OTW
LS 4.0-40 OTW	LS 4.0-120 OTW	L 5.0-40 OTW
L 4.0-40 OTW	L 4.0-120 OTW	LS 5.0-60 OTW
LS 4.0-60 OTW	LS 4.0-150 OTW	L 5.0-60 OTW
L 4.0-60 OTW	L 4.0-150 OTW	LS 5.0-80 OTW
LS 4.0-80 OTW		L 5.0-80 OTW

LS 5.0-100 OTW
L 5.0-100 OTW
LS 5.0-120 OTW
L 5.0-120 OTW
LS 5.0-150 OTW
L 5.0-150 OTW

LS 6.0-20 OTW
L 6.0-20 OTW
LS 6.0-40 OTW
L 6.0-40 OTW
LS 6.0-60 OTW
L 6.0-60 OTW
LS 6.0-80 OTW
L 6.0-80 OTW
LS 6.0-100 OTW
L 6.0-100 OTW
LS 6.0-120 OTW
L 6.0-120 OTW
LS 6.0-150 OTW
L 6.0-150 OTW

LS 7.0-20 OTW
L 7.0-20 OTW
LS 7.0-40 OTW
L 7.0-40 OTW
LS 7.0-60 OTW
L 7.0-60 OTW
LS 7.0-80 OTW
L 7.0-80 OTW
LS 7.0-100 OTW
L 7.0-100 OTW
LS 7.0-120 OTW
L 7.0-120 OTW
LS 7.0-150 OTW
L 7.0-150 OTW

LS 8.0-20 OTW
L 8.0-20 OTW
LS 8.0-40 OTW
L 8.0-40 OTW
LS 8.0-60 OTW
L 8.0-60 OTW
LS 8.0-80 OTW

L 8.0-80 OTW
LS 8.0-100 OTW
L 8.0-100 OTW
LS 8.0-120 OTW
L 8.0-120 OTW
LS 8.0-150 OTW
L 8.0-150 OTW

LS 9.0-20 OTW
L 9.0-20 OTW
LS 9.0-40 OTW
L 9.0-40 OTW
LS 9.0-60 OTW
L 9.0-60 OTW

LS 10.0-20 OTW
L 10.0-20 OTW
LS 10.0-40 OTW
L 10.0-40 OTW
LS 10.0-60 OTW
L 10.0-60 OTW

Legflow OTW 0.014''

L 2.0-40 OTW
L 2.0-80 OTW
L 2.0-120 OTW
L 2.0-150 OTW
L 2.5-40 OTW
L 2.5-80 OTW
L 2.5-120 OTW
L 2.5-150 OTW
L 3.0-40 OTW
L 3.0-80 OTW
L 3.0-120 OTW
L 3.0-150 OTW
L 3.5-40 OTW
L 3.5-80 OTW
L 3.5-120 OTW
L 3.5-150 OTW

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	

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: **LEGFLOW® OTW**
 Paclitaxel Releasing Peripheral Balloon Dilatation Catheter

Class; Rule: III; Rule 13

EMDN code C01040299

GMDN Code: 62551

UMDNS code 10727

Basic UDI 590619015LEGFLOWOTWA2

Types/ Sizes:

Balloon length (mm)	OTW 0.035" Catheter length 800 mm (LS) or 1350 mm (L)						
	Balloon diameter (mm)						
	4.00 mm	5.00 mm	6.00 mm	7.00 mm	8.00 mm	9.00 mm	10.00 mm
20 mm	L 4.0-20 OTW LS 4.0-20 OTW	L 5.0-20 OTW LS 5.0-20 OTW	L 6.0-20 OTW LS 6.0-20 OTW	L 7.0-20 OTW LS 7.0-20 OTW	L 8.0-20 OTW LS 8.0-20 OTW	L 9.0-20 OTW LS 9.0-20 OTW	L 10.0-20 OTW LS 10.0-20 OTW
40 mm	L 4.0-40 OTW LS 4.0-40 OTW	L 5.0-40 OTW LS 5.0-40 OTW	L 6.0-40 OTW LS 6.0-40 OTW	L 7.0-40 OTW LS 7.0-40 OTW	L 8.0-40 OTW LS 8.0-40 OTW	L 9.0-40 OTW LS 9.0-40 OTW	L 10.0-40 OTW LS 10.0-40 OTW
60 mm	L 4.0-60 OTW LS 4.0-60 OTW	L 5.0-60 OTW LS 5.0-60 OTW	L 6.0-60 OTW LS 6.0-60 OTW	L 7.0-60 OTW LS 7.0-60 OTW	L 8.0-60 OTW LS 8.0-60 OTW	L 9.0-60 OTW LS 9.0-60 OTW	L 10.0-60 OTW LS 10.0-60 OTW
80 mm	L 4.0-80 OTW LS 4.0-80 OTW	L 5.0-80 OTW LS 5.0-80 OTW	L 6.0-80 OTW LS 6.0-80 OTW	L 7.0-80 OTW LS 7.0-80 OTW	L 8.0-80 OTW LS 8.0-80 OTW	L 9.0-80 OTW LS 9.0-80 OTW	L 10.0-80 OTW LS 10.0-80 OTW
100 mm	L 4.0-100 OTW LS 4.0-100 OTW	L 5.0-100 OTW LS 5.0-100 OTW	L 6.0-100 OTW LS 6.0-100 OTW	L 7.0-100 OTW LS 7.0-100 OTW	L 8.0-100 OTW LS 8.0-100 OTW	L 9.0-100 OTW LS 9.0-100 OTW	L 10.0-100 OTW LS 10.0-100 OTW
120 mm	L 4.0-120 OTW LS 4.0-120 OTW	L 5.0-120 OTW LS 5.0-120 OTW	L 6.0-120 OTW LS 6.0-120 OTW	L 7.0-120 OTW LS 7.0-120 OTW	L 8.0-120 OTW LS 8.0-120 OTW	L 9.0-120 OTW LS 9.0-120 OTW	L 10.0-120 OTW LS 10.0-120 OTW
150 mm	L 4.0-150 OTW LS 4.0-150 OTW	L 5.0-150 OTW LS 5.0-150 OTW	L 6.0-150 OTW LS 6.0-150 OTW	L 7.0-150 OTW LS 7.0-150 OTW	L 8.0-150 OTW LS 8.0-150 OTW	-	-

Balloon length (mm)	OTW 0.018" Catheter length 1200 (LS) or 1500 mm (L)					
	Balloon diameter (mm)					
	2.00 mm	3.00 mm	4.00 mm	5.00 mm	6.00 mm	7.00 mm
40 mm	L 18 2.0-40 LS 18 2.0-40	L 18 3.0-40 LS 18 3.0-40	L 18 4.0-40 LS 18 4.0-40	L 18 5.0-40 LS 18 5.0-40	L 18 6.0-40 LS 18 6.0-40	L 18 7.0-40 LS 18 7.0-40
60 mm	L 18 2.0-60 LS 18 2.0-60	L 18 3.0-60 LS 18 3.0-60	L 18 4.0-60 LS 18 4.0-60	L 18 5.0-60 LS 18 5.0-60	L 18 6.0-60 LS 18 6.0-60	L 18 7.0-60 LS 18 7.0-60
80 mm	L 18 2.0-80 LS 18 2.0-80	L 18 3.0-80 LS 18 3.0-80	L 18 4.0-80 LS 18 4.0-80	L 18 5.0-80 LS 18 5.0-80	L 18 6.0-80 LS 18 6.0-80	L 18 7.0-80 LS 18 7.0-80
100 mm	L 18 2.0-100 LS 18 2.0-100	L 18 3.0-100 LS 18 3.0-100	L 18 4.0-100 LS 18 4.0-100	L 18 5.0-100 LS 18 5.0-100	L 18 6.0-100 LS 18 6.0-100	L 18 7.0-100 LS 18 7.0-100
120 mm	L 18 2.0-120 LS 18 2.0-120	L 18 3.0-120 LS 18 3.0-120	L 18 4.0-120 LS 18 4.0-120	L 18 5.0-120 LS 18 5.0-120	L 18 6.0-120 LS 18 6.0-120	L 18 7.0-120 LS 18 7.0-120
150 mm	L 18 2.0-150 LS 18 2.0-150	L 18 3.0-150 LS 18 3.0-150	L 18 4.0-150 LS 18 4.0-150	L 18 5.0-150 LS 18 5.0-150	L 18 6.0-150 LS 18 6.0-150	L 18 7.0-150 LS 18 7.0-150

Balloon length (mm)	OTW 0.014" Catheter length 1500mm			
	Balloon diameter (mm)			
	2.00 mm	2.50 mm	3.00 mm	3.50 mm
8 mm	L 2.0-8 OTW	L 2.5-8 OTW	L 3.0-8 OTW	L 3.5-8 OTW
10 mm	L 2.0-10 OTW	L 2.5-10 OTW	L 3.0-10 OTW	L 3.5-10 OTW
20 mm	L 2.0-20 OTW	L 2.5-20 OTW	L 3.0-20 OTW	L 3.5-20 OTW
30 mm	L 2.0-30 OTW	L 2.5-30 OTW	L 3.0-30 OTW	L 3.5-30 OTW
40 mm	L 2.0-40 OTW	L 2.5-40 OTW	L 3.0-40 OTW	L 3.5-40 OTW
60 mm	L 2.0-60 OTW	L 2.5-60 OTW	L 3.0-60 OTW	L 3.5-60 OTW
80 mm	L 2.0-80 OTW	L 2.5-80 OTW	L 3.0-80 OTW	L 3.5-80 OTW
100 mm	L 2.0-100 OTW	L 2.5-100 OTW	L 3.0-100 OTW	L 3.5-100 OTW
120 mm	L 2.0-120 OTW	L 2.5-120 OTW	L 3.0-120 OTW	L 3.5-120 OTW
150 mm	L 2.0-150 OTW	L 2.5-150 OTW	L 3.0-150 OTW	L 3.5-150 OTW
200 mm	L 2.0-200 OTW	L 2.5-200 OTW	-	-

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.

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-218/2020	EC-Design Examination	
EC Certificate	1434-MDD-219/2020	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



1434

Digitally signed by Monika
Mroczkiewicz
Date: 2023.04.25
14:20:15 +02'00'

Bonn, date next to signature

Declaration bears as qualified signature

by: Monika MROCKIEWICZ, Quality & Regulatory Affairs Director

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: **LEGFLOW® RX**
Paclitaxel Releasing Peripheral Balloon Dilatation Catheter

Class; Rule: III; Rule 13

EMDN code C01040299

GMDN Code: 62551

UMDNS code 10727

Basic UDI 590619015LEGFLOWRXJM

Types/ Sizes:

Balloon length (mm)	Balloon diameter (mm)					
	2.00	2.25	2.50	2.75	3.00	3.50
8	L 2.0-8 RX	L 2.25-8 RX	L 2.50-8 RX	L 2.75-8 RX	L 3.0-8 RX	L 3.5-8 RX
10	L 2.0-10 RX	L 2.25-10 RX	L 2.50-10 RX	L 2.75-10 RX	L 3.0-10 RX	L 3.5-10 RX
20	L 2.0-20 RX	L 2.25-20 RX	L 2.50-20 RX	L 2.75-20 RX	L 3.0-20 RX	L 3.5-20 RX
30	L 2.0-30 RX	L 2.25-30 RX	L 2.50-30 RX	L 2.75-30 RX	L 3.0-30 RX	L 3.5-30 RX
40	L 2.0-40 RX	L 2.25-40 RX	L 2.50-40 RX	L 2.75-40 RX	L 3.0-40 RX	L 3.5-40 RX
60	L 2.0-60 RX	L 2.25-60 RX	L 2.50-60 RX	L 2.75-60 RX	L 3.0-60 RX	L 3.5-60 RX
80	L 2.0-80 RX	L 2.25-80 RX	L 2.50-80 RX	L 2.75-80 RX	L 3.0-80 RX	L 3.5-80 RX
100	L 2.0-100 RX	L 2.25-100 RX	L 2.50-100 RX	L 2.75-100 RX	L 3.0-100 RX	L 3.5-100 RX
120	L 2.0-120 RX	L 2.25-120 RX	L 2.50-120 RX	L 2.75-120 RX	L 3.0-120 RX	L 3.5-120 RX
150	L 2.0-150 RX	L 2.25-150 RX	L 2.50-150 RX	L 2.75-150 RX	L 3.0-150 RX	L 3.5-150 RX
200	L 2.0-200 RX	L 2.25-200 RX	L 2.50-200 RX	L 2.75-200 RX	L 3.0-200 RX	L 3.5-200 RX

Balloon length (mm)	Balloon diameter (mm)				
	4.00	4.50	5.00	6.00	7.00
8	L 4.0-8 RX	L 4.5-8 RX	L 5.0-8 RX	L 6.0-8 RX	L 7.0-8 RX
10	L 4.0-10 RX	L 4.5-10 RX	L 5.0-10 RX	L 6.0-10 RX	L 7.0-10 RX
20	L 4.0-20 RX	L 4.5-20 RX	L 5.0-20 RX	L 6.0-20 RX	L 7.0-20 RX
30	L 4.0-30 RX	L 4.5-30 RX	L 5.0-30 RX	L 6.0-30 RX	L 7.0-30 RX
40	L 4.0-40 RX	L 4.5-40 RX	L 5.0-40 RX	L 6.0-40 RX	L 7.0-40 RX
60	L 4.0-60 RX	L 4.5-60 RX	L 5.0-60 RX	L 6.0-60 RX	L 7.0-60 RX
80	L 4.0-80 RX	L 4.5-80 RX	L 5.0-80 RX	L 6.0-80 RX	L 7.0-80 RX
100	L 4.0-100 RX	L 4.5-100 RX	L 5.0-100 RX	L 6.0-100 RX	L 7.0-100 RX
120	L 4.0-120 RX	L 4.5-120 RX	L 5.0-120 RX	L 6.0-120 RX	L 7.0-120 RX
150	L 4.0-150 RX	L 4.5-150 RX	L 5.0-150 RX	L 6.0-150 RX	L 7.0-150 RX
200	L 4.0-200 RX	L 4.5-200 RX	L 5.0-200 RX	L 6.0-200 RX	L 7.0-200 RX

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.

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-216/2020	EC-Design Examination	
EC Certificate	1434-MDD-217/2020	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



Bonn, date next to signature

**Declaration bears as qualified
signature**



Digitally signed by Monika
Mroczkiewicz
Date: 2023.04.25
14:20:47 +02'00'

by: Monika MROCKIEWICZ, Quality & Regulatory Affairs Director



CERTIFICATE

EC Certificate No. 1434-MDD-218/2020

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

**LEGFLOW OTW Paclitaxel Releasing Peripheral Balloon Dilatation
Catheter**

The list of medical devices covered by this certificate is provided in the Annex no. 1, 2 and 3

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

Validity of the Certificate: from 19.05.2020 to 27.05.2024

The date of issue of the Certificate: 19.05.2020

The date of the first issue of the Certificate: 30.06.2011



Issued under the Contract No. MD-170/2019
Application No: 260/2019
Certificate bears the qualified person signature.
Warsaw, 19/05/2020
Module H1


mgr Anna Wyroba
Vice-President



ANNEX No. 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No **1434-MDD-218/2020**

List of medical devices covered by the certificate:

OTW 0.035" Catheter length 800 mm (LS) or 1350 mm (L)							
Balloon Length (mm)	Balloon Diameter (mm)						
	4.00	5.00	6.00	7.00	8.00	9.00	10.00
20	L 4.0-20 OTW LS 4.0-20 OTW	L 5.0-20 OTW LS 5.0-20 OTW	L 6.0-20 OTW LS 6.0-20 OTW	L 7.0-20 OTW LS 7.0-20 OTW	L 8.0-20 OTW LS 8.0-20 OTW	L 9.0-20 OTW LS 9.0-20 OTW	L 10.0-20 OTW LS 10.0-20 OTW
40	L 4.0-40 OTW LS 4.0-40 OTW	L 5.0-40 OTW LS 5.0-40 OTW	L 6.0-40 OTW LS 6.0-40 OTW	L 7.0-40 OTW LS 7.0-40 OTW	L 8.0-40 OTW LS 8.0-40 OTW	L 9.0-40 OTW LS 9.0-40 OTW	L 10.0-40 OTW LS 10.0-40 OTW
60	L 4.0-60 OTW LS 4.0-60 OTW	L 5.0-60 OTW LS 5.0-60 OTW	L 6.0-60 OTW LS 6.0-60 OTW	L 7.0-60 OTW LS 7.0-60 OTW	L 8.0-60 OTW LS 8.0-60 OTW	L 9.0-60 OTW LS 9.0-60 OTW	L 10.0-60 OTW LS 10.0-60 OTW
80	L 4.0-80 OTW LS 4.0-80 OTW	L 5.0-80 OTW LS 5.0-80 OTW	L 6.0-80 OTW LS 6.0-80 OTW	L 7.0-80 OTW LS 7.0-80 OTW	L 8.0-80 OTW LS 8.0-80 OTW	L 9.0-80 OTW LS 9.0-80 OTW	L 10.0-80 OTW LS 10.0-80 OTW
100	L 4.0-100 OTW LS 4.0-100 OTW	L 5.0-100 OTW LS 5.0-100 OTW	L 6.0-100 OTW LS 6.0-100 OTW	L 7.0-100 OTW LS 7.0-100 OTW	L 8.0-100 OTW LS 8.0-100 OTW	L 9.0-100 OTW LS 9.0-100 OTW	L 10.0-100 OTW LS 10.0-100 OTW
120	L 4.0-120 OTW LS 4.0-120 OTW	L 5.0-120 OTW LS 5.0-120 OTW	L 6.0-120 OTW LS 6.0-120 OTW	L 7.0-120 OTW LS 7.0-120 OTW	L 8.0-120 OTW LS 8.0-120 OTW	L 9.0-120 OTW LS 9.0-120 OTW	L 10.0-120 OTW LS 10.0-120 OTW
150	L 4.0-150 OTW LS 4.0-150 OTW	L 5.0-150 OTW LS 5.0-150 OTW	L 6.0-150 OTW LS 6.0-150 OTW	L 7.0-150 OTW LS 7.0-150 OTW	L 8.0-150 OTW LS 8.0-150 OTW	-	-



Issued under the Contract No. [MD-170/2019](#)
 Application No: [260/2019](#)
 Certificate bears the qualified person signature.
 Warsaw, [19/05/2020](#)

Anna Wyroba
 mgr Anna Wyroba
 Vice-President



ANNEX No. 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No **1434-MDD-218/2020**

List of medical devices covered by the certificate:

OTW 0.018" Catheter length 1200 mm (LS) or 1500 mm (L)						
Balloon Length (mm)	Balloon Diameter (mm)					
	2.0	3.0	4.0	5.0	6.0	7.0
40	L 18 2.0-40 LS 18 2.0-40	L 18 3.0-40 LS 18 3.0-40	L 18 4.0-40 LS 18 4.0-40	L 18 5.0-40 LS 18 5.0-40	L 18 6.0-40 LS 18 6.0-40	L 18 7.0-40 LS 18 7.0-40
60	L 18 2.0-60 LS 18 2.0-60	L 18 3.0-60 LS 18 3.0-60	L 18 4.0-60 LS 18 4.0-60	L 18 5.0-60 LS 18 5.0-60	L 18 6.0-60 LS 18 6.0-60	L 18 7.0-60 LS 18 7.0-60
80	L 18 2.0-80 LS 18 2.0-80	L 18 3.0-80 LS 18 3.0-80	L 18 4.0-80 LS 18 4.0-80	L 18 5.0-80 LS 18 5.0-80	L 18 6.0-80 LS 18 6.0-80	L 18 7.0-80 LS 18 7.0-80
100	L 18 2.0-100 LS 18 2.0-100	L 18 3.0-100 LS 18 3.0-100	L 18 4.0-100 LS 18 4.0-100	L 18 5.0-100 LS 18 5.0-100	L 18 6.0-100 LS 18 6.0-100	L 18 7.0-100 LS 18 7.0-100
120	L 18 2.0-120 LS 18 2.0-120	L 18 3.0-120 LS 18 3.0-120	L 18 4.0-120 LS 18 4.0-120	L 18 5.0-120 LS 18 5.0-120	L 18 6.0-120 LS 18 6.0-120	L 18 7.0-120 LS 18 7.0-120
150	L 18 2.0-150 LS 18 2.0-150	L 18 3.0-150 LS 18 3.0-150	L 18 4.0-150 LS 18 4.0-150	L 18 5.0-150 LS 18 5.0-150	L 18 6.0-150 LS 18 6.0-150	L 18 7.0-150 LS 18 7.0-150



Issued under the Contract No. MD-170/2019
Application No: 260/2019
Certificate bears the qualified person signature.
Warsaw, 19/05/2020


mgr Anna Wyroba
Vice-President



ANNEX No. 3 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No **1434-MDD-218/2020**

List of medical devices covered by the certificate:

OTW 0.014" Catheter length 1500 mm				
Balloon Length (mm)	Balloon Diameter (mm)			
	2.0	2.5	3.0	3.5
8	L 2.0-8 OTW	L 2.5-8 OTW	L 3.0-8 OTW	L 3.5-8 OTW
10	L 2.0-10 OTW	L 2.5-10 OTW	L 3.0-10 OTW	L 3.5-10 OTW
20	L 2.0-20 OTW	L 2.5-20 OTW	L 3.0-20 OTW	L 3.5-20 OTW
30	L 2.0-30 OTW	L 2.5-30 OTW	L 3.0-30 OTW	L 3.5-30 OTW
40	L 2.0-40 OTW	L 2.5-40 OTW	L 3.0-40 OTW	L 3.5-40 OTW
60	L 2.0-60 OTW	L 2.5-60 OTW	L 3.0-60 OTW	L 3.5-60 OTW
80	L 2.0-80 OTW	L 2.5-80 OTW	L 3.0-80 OTW	L 3.5-80 OTW
100	L 2.0-100 OTW	L 2.5-100 OTW	L 3.0-100 OTW	L 3.5-100 OTW
120	L 2.0-120 OTW	L 2.5-120 OTW	L 3.0-120 OTW	L 3.5-120 OTW
150	L 2.0-150 OTW	L 2.5-150 OTW	L 3.0-150 OTW	L 3.5-150 OTW
200	L 2.0-200 OTW	L 2.5-200 OTW	L 3.0-200 OTW	L 3.5-200 OTW



Issued under the Contract No. [MD-170/2019](#)
Application No: [260/2019](#)
Certificate bears the qualified person signature.
Warsaw, [19/05/2020](#)


mgr Anna Wyroba
Vice-President



CERTIFICATE

EC Certificate No. 1434-MDD-219/2020

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 devices, class III

**LEGFLOW OTW Paclitaxel Releasing Peripheral Balloon Dilatation
Catheter**

The list of medical devices covered by this certificate is provided in the Annex no. 1, 2 and 3 to EC Design-examination Certificate No. 1434-MDD-218/2020

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

Validity of the Certificate: from 19.05.2020 to 27.05.2024

The date of issue of the Certificate: 19.05.2020

The date of the first issue of the Certificate: 30.06.2011



Issued under the Contract No. MD-170/2019
Application No: 260/2019
Certificate bears the qualified person signature.
Warsaw, 19/05/2020
Module H2/3/4/5


mgr Anna Wyroba
Vice-President



CERTIFICATE

EC Certificate No. 1434-MDD-216/2020

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

**LEGFLOW RX Paclitaxel Releasing Peripheral Balloon Dilatation
Catheter**

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

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

Validity of the Certificate: from 19.05.2020 to 27.05.2024

The date of issue of the Certificate: 19.05.2020

The date of the first issue of the Certificate: 20.11.2012



Issued under the Contract No. MD-209/2019
Application No: 338/2019
Certificate bears the qualified person signature.
Warsaw, 19/05/2020
Module H1


mgr Anna Wyroba
Vice-President



ANNEX No. 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-216/2020

List of medical devices covered by the certificate:

		Balloon Diameter (mm)					
		2.00	2.25	2.50	2.75	3.00	3.50
Balloon Length (mm)	8	L 2.0-8 RX	L 2.25-8 RX	L 2.50-8 RX	L 2.75-8 RX	L 3.0-8 RX	L 3.5-8 RX
	10	L 2.0-10 RX	L 2.25-10 RX	L 2.50-10 RX	L 2.75-10 RX	L 3.0-10 RX	L 3.5-10 RX
	20	L 2.0-20 RX	L 2.25-20 RX	L 2.50-20 RX	L 2.75-20 RX	L 3.0-20 RX	L 3.5-20 RX
	30	L 2.0-30 RX	L 2.25-30 RX	L 2.50-30 RX	L 2.75-30 RX	L 3.0-30 RX	L 3.5-30 RX
	40	L 2.0-40 RX	L 2.25-40 RX	L 2.50-40 RX	L 2.75-40 RX	L 3.0-40 RX	L 3.5-40 RX
	60	L 2.0-60 RX	L 2.25-60 RX	L 2.50-60 RX	L 2.75-60 RX	L 3.0-60 RX	L 3.5-60 RX
	80	L 2.0-80 RX	L 2.25-80 RX	L 2.50-80 RX	L 2.75-80 RX	L 3.0-80 RX	L 3.5-80 RX
	100	L 2.0-100 RX	L 2.25-100 RX	L 2.50-100 RX	L 2.75-100 RX	L 3.0-100 RX	L 3.5-100 RX
	120	L 2.0-120 RX	L 2.25-120 RX	L 2.50-120 RX	L 2.75-120 RX	L 3.0-120 RX	L 3.5-120 RX
	150	L 2.0-150 RX	L 2.25-150 RX	L 2.50-150 RX	L 2.75-150 RX	L 3.0-150 RX	L 3.5-150 RX
200	L 2.0-200 RX	L 2.25-200 RX	L 2.50-200 RX	L 2.75-200 RX	L 3.0-200 RX	L 3.5-200 RX	

		Balloon Diameter (mm)				
		4.00	4.50	5.00	6.00	7.00
Balloon Length (mm)	8	L 4.0-8 RX	L 4.5-8 RX	L 5.0-8 RX	L 6.0-8 RX	L 7.0-8 RX
	10	L 4.0-10 RX	L 4.5-10 RX	L 5.0-10 RX	L 6.0-10 RX	L 7.0-10 RX
	20	L 4.0-20 RX	L 4.5-20 RX	L 5.0-20 RX	L 6.0-20 RX	L 7.0-20 RX
	30	L 4.0-30 RX	L 4.5-30 RX	L 5.0-30 RX	L 6.0-30 RX	L 7.0-30 RX
	40	L 4.0-40 RX	L 4.5-40 RX	L 5.0-40 RX	L 6.0-40 RX	L 7.0-40 RX
	60	L 4.0-60 RX	L 4.5-60 RX	L 5.0-60 RX	L 6.0-60 RX	L 7.0-60 RX
	80	L 4.0-80 RX	L 4.5-80 RX	L 5.0-80 RX	L 6.0-80 RX	L 7.0-80 RX
	100	L 4.0-100 RX	L 4.5-100 RX	L 5.0-100 RX	L 6.0-100 RX	L 7.0-100 RX
	120	L 4.0-120 RX	L 4.5-120 RX	L 5.0-120 RX	L 6.0-120 RX	L 7.0-120 RX
	150	L 4.0-150 RX	L 4.5-150 RX	L 5.0-150 RX	L 6.0-150 RX	L 7.0-150 RX
200	L 4.0-200 RX	L 4.5-200 RX	L 5.0-200 RX	L 6.0-200 RX	L 7.0-200 RX	



Issued under the Contract No. MD-209/2019

Application No: 338/2019

Certificate bears the qualified person signature.

Warsaw, 19/05/2020

Anna Wyroba
mgr Anna Wyroba
Vice-President



CERTIFICATE

EC Certificate No. 1434-MDD-217/2020

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 devices, class III

**LEGFLOW RX Paclitaxel Releasing Peripheral Balloon Dilatation
Catheter**

*The list of medical devices covered by this certificate is provided in the annex no. 1 to EC Design-examination
Certificate No. 1434-MDD-216/2020*

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

Validity of the Certificate: from 19.05.2020 to 27.05.2024

The date of issue of the Certificate: 19.05.2020

The date of the first issue of the Certificate: 20.11.2012

CE 1434

Issued under the Contract No. MD-209/2019
Application No: 338/2019
Certificate bears the qualified person signature.
Warsaw, 19/05/2020
Module H2/3/4/5


mgr Anna Wyroba
Vice-President