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

CE 1434

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

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.05.26 15:06:16 +02'00'

mgr Anna Wyroba
Vice-President

POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.

EC SERTIFIKATAS Nr. 1434-MDD-2018/2020

Direktyva 93/42/EEC dėl medicinos prietaisų.

PCBC S.A. patvirtina, kad

CARDIONOVUM GmbG
Am Bonner Bogen 2
53227 Bonn
Vokietija

medicinos priemonei, klasė III:
LEGFLOW OTW Paklitakseliu dengti periferiniai balioniniai kateteriai

buvo patikrinti remiantis Priedu II (Skyrius 4) Direktyvos 93/42/EEC Lenkijos įstatymais ir atitinka Direktyvos reikalavimus

Šis sertifikatas galioja nuo: 19.05.2020 iki 27.05.2024

Sertifikato išdavimo data: 19.05.2020

Pirmo sertifikato išdavimo data: 30.06.2011

/Parašas/

Vertimas tikras

Direktorė
Vestina Strakšytė

KONFIDENCIALU

CARDIONOVUM®
Life deserves the best

Bonn, 06.03.2024

To Whom it May Concern,

MANUFACTURER STATEMENT

We, CARDIONOVUM GmbH, hereby inform, that the process of CE certification according to the requirements of Regulation (EU) 2017/745 (MDR) of our devices has been started in 2023.

Taking into account that CARDIONOVUM GmbH had met all the transitional provisions described in Regulation EU 2023/607 amending Regulations 2017/745, among others, the contract for the MDR certification has been signed with Notified Body, **CARDIONOVUM has been granted with the CE certificates issued under Directive 93/42/EEC (MDD) extension until 31 December 2027.**

Official extension letters, issued by Polish Centre for Testing and Certification, Notified Body of CARDIONOVUM GmbH are attached to this letter.

In case of any questions related to the CE certificates, do not hesitate to contact Monika Mroczkiewicz, monika.mroczkiewicz@cardionovum.com.

Best regards,

Digitally signed by
kiewicz
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)0'

Quality and Regulatory Affairs Director,
CARDIONOVUM GmbH

KOPIJA TIKRA

1. Confirmation_Cardionovum_APERTO OTW
2. Confirmation_Cardionovum_LEGFLOW OTW
3. Confirmation_Cardionovum_LEGFLOW RX
4. Confirmation_Cardionovum_RESTORE
5. Confirmation_Cardionovum_XLIMUS

CARDIONOVUM GmbH
Am Bonner Bogen 2
53227 Bonn, Germany
Phone: +49 (0) 228 / 90 90 59 - 0
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Geschäftsführer
Miquel Craven-Bartle Capella, (CEO)

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

KONFIDENCIALU

POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

KOPIJA TIKRA

Direktorė

KW/MC/2024/0084

w, 29-02-2024

Manufacturer Name: Cardionovum GmbH

Adress: Am Bonner Bogen 2,

53227 Bonn, Germany

Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Polish Centre for Testing and Certification, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1434 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Cardionovum GmbH Am Bonner Bogen 2, 53227 Bonn, Germany

SRN Number (if available): DE-MF-000005316

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the

applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Elektronicznie podpisany
:ez Tomasz Artur Koeber
ta: 2024.02.29 10:49:14
1'00'

Tomasz Koeber

Head of Medical Device Certification Department

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
LEGFLOW OTW Paclitaxel Releasing Peripheral Balloon Dilatation Catheter	Class III	N/A	1434-MDD-218/2020 NB 1434 1434-MDD-219/2020 NB 1434

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	NA	NA	NA

KOPIJA TIKRA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
29-02-2024	KW/MC/2024/0084	Initial issue