CARDIONOVUM®
Life deserves the best

Place, date: Bonn, 18.03.2024

To whom it may concern

STATEMENT

CARDIONOVUM GmbH, Am Bonner Bogen 2, 53227 Bonn, Germany, as the legal manufacturer of medical device:

RESTORE DEB Paclitaxel Releasing PTCA Balloon Catheter

hereby declares that:

1. the relevant device continue to comply with Directive 93/42/EEC,
2. there is no significant change in the design and intended use of the device,
3. it does not pose an unacceptable risk to the health or safety of patients, users, or other persons or to other matters relevant to the protection of public health,
4. quality management system by Article 10(9) of the MDR was implemented in the company. It is certificated by Notified Body No.1434 PCBC S.A. The ISO 13485 QMS certificate no. is M - 62/3/2023 issued on 02.02.2023,
5. CARDIONOVUM GmbH has made an official application to a notified body PCBC S.A. No.1434 on 13.02.2024. The device will be assessed within the scope of Annex IX (I) and IX (II) to MDR,
6. written agreement has been signed between the notified body PCBC S.A. NB No.1434 and CARDIONOVUM GmbH on 22.02.2024,
7. in order to confirm the validity of this declaration, please contact:
Monika Mroczkiewicz, Director of the Quality & Regulatory Affairs Department
Email: Monika.Mroczkiewicz@cardionovum.com

For and behalf of CARDIONOVUM GmbH

Digitally signed by
Monika Mroczkiewicz
Date: 2024.03.18
16:49:54 +01'00'

Monika Mroczkiewicz
Director of the Quality & Regulatory Affairs Department

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Geschäftsführer
Miquel Craven-Bartle Capella

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