Self-declaration of compliance towards transitional provisions under Regulation (EU) 2023/607 amending Regulations (EU) 2017/745

This Self Declaration is issued under the sole responsibility of Cortex Technology Aps and declares that the devices listed below are in conformity with the Regulation (EU) 2023/607 amending Regulations (EU) 2017/745, on medical devices.

Furthermore, manufacturer explicitly declares that,

a) devices continue to comply with Directive 93/42/EEC
b) there are no significant changes in the design and intended purpose devices listed below
c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health
d) the certificates were valid on 26 May 2021 and has not been suspended nor withdrawn. The certificate expired after May 26, 2021 (20221005)
e) in the case of devices covered by MDD certificates expired prior 20 March 2023, and for which no MDR agreement has been signed before the expiry of the MDD certificate, this declaration also confirms that: competent authority of a Member State had granted a derogation/exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR
   Or
   before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII to this Regulation for the conformity assessment
f) has a quality management system in accordance with Article 10(9)
g) requirements of Regulation (EU) 2017/745 relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are met.

Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
CryoPro Maxi / 5710188020018E CryoPro Mini / 5710188020028G	Class IIa according to rule 9 (Active therapeutic devices intended to exchange or administer energy)	CryoPro Maxi CryalJet Maxi EROND CRYO maxi CryoPro Mini CryalJet Maxi EROND CRYO mini	Certificate number: #10000380739-PA-NA-DNK; NB number NB: 2460; Expiry date: 20221005 (YYYYMMDD)

Date of Signature: 05-04-2023
DD-mm-YYYY

Place of Signature: Aalborg, Denmark
Place, Country

Signed on behalf of Cortex Technology Aps:

Morten Fjorback, Director of R&D and QA/RA