

Declaration of conformity  
in accordance with EU Regulation MDR 2017/745, Art. 120 and  
amending Regulation 2023/607 on  
medical devices

**Manufacturer:**

4D Werk GmbH  
Alemannenstrasse 7  
D-78606 Seitingen-Oberflacht

**Designation of the product:**

Cryofos, Cryofos Mobile

**UDI-DI Cryofos office device:**

4262476130001

**UDI-DI Cryofos mobile device:**

4262476130018

**Class of the product:**

Ila

**No. of the notified body:**

0483

**Notified body:**

mdc medical device certification GmbH,  
Kriegerstraße 6, D-70191 Stuttgart

**Applied standards:**

DIN EN ISO 13485:2021  
DIN EN ISO 14971:2019  
DIN EN 60601-1:2013/A1:2020

**Conformity assessment procedure:**

Directive 93/42/EEC Annex V point 3 in the context of the transitional provisions according to MDR 2017/745 Art. 120 and the amending regulation 2023/607.

**Declaration of Conformity:**

We declare under our sole responsibility and in accordance with Article 120(3) and (3a) of Regulation (EU) 2017/745 that the products Cryofos and Cryofos Mobile were assessed and classified as Class IIa medical devices according to Article 122 of Regulation (EU) 2017/745 in conjunction with Directive 93/42/EEC on medical devices prior to 26 May 2021.

According to Article 120 of Regulation (EU) 2017/745 on medical devices and Amending Regulation 2023/607, products certified under the previous Directive 93/42/EEC (MDD) that have not undergone significant changes may continue to be placed on the market until 26 May 2027.

The conformity assessment was carried out in accordance with EU Directive 93/42/EEC Annex V. The conditions of Article 120(3c) and (3d) of Regulation (EU) 2017/745 are met.

The products are marked with the following conformity mark:

**CE 0483**

Seitingen-Oberflacht, 26.09.2024

Manufacturer's stamp and signature of the management:

  
**4D Werk GmbH**  
Alemannenstrasse 7  
Telefon:  
+49 (0)7464 - 9898849  
D - 78606 SEITINGEN - OBERFLACHT  
E-Mail: info@4dwerk.de • www.4dwerk.de

*Uwe Dessecker*  
Uwe Dessecker (Sep 26, 2024 15:14 GMT+2)