EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
7260GB448260310	7260AU12F	2026-03-10	2030-06-30

This is to certify that the quality system of

Cryotherm GmbH & Co. KG

Euteneuen 4, 57548 Kirchen (Sieg), Germany

SRN: DE-MF-000018064

For design & development, manufacturing and final product inspection/testing of

Medical devices/groups of medical devices at locations as listed on the following pages

has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX, Chapters I and III of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2026-03-10

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Annika Chill
Certification Body Operations

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact medcert-info@dnv.com

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. 820111 EN Rev 9 2026.02.24

Certificate no.: 7260GB448260310
Place and date: Hamburg, 2026-03-10

Sites covered by this certificate

Cryotherm GmbH & Co. KG, Euteneuen 4, 57548 Kirchen (Sieg, Germany

Preceding certificate

Certificate no.	Issue date	Identification of changes
N/A	N/A	N/A

Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1212	V0499	CLINICAL USE CONTAINERS (NON—IVD) — OTHER