EU QUALITY ASSURANCE CERTIFICATE

Certificate no.:	Initial certification date:	Valid Until:
C678911	30 April 2026	29 April 2031

This is to certify that the quality system of

Medfor Products Ltd

Unit 2, Gresham Industrial Estate, Eastern Road, Aldershot, GU12 4YD, United Kingdom

SRN: GB-MF-000022996

For production and final product inspection/testing of:

Manufacture and testing of sterile plastic containers for the transit and storage of human tissues prior to transplantation.

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex XI, (Part A) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 30 April 2026

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Khanpara B.C.

Bhautik Khanpara
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

Certificate no.: C678911
Place and date: Høvik, 30 April 2026

Jurisdiction

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices “by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	**Original Certificate**	**3088626**	30 April 2026

Products covered by this Certificate:

Product Description	Product Name	Class
Plastic containers for the transit and storage of human organs and tissues prior to transplantation	Sterile & non-sterile containers for the transit and storage of human organs and tissues prior to transplantation.	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Medfor Products Ltd	Unit 2, Gresham Industrial Estate, Eastern Road, Aldershot, GU12 4YD, United Kingdom

EU Representative
Emergo Europe, Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. The Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system.