



EU QUALITY ASSURANCE CERTIFICATE

Certificate no.:
C589510

Initial certification date:
22 October 2025

Valid Until:
21 October 2030

This is to certify that the quality system of

Biolife, L.L.C.

8163 25th Court East Sarasota,
Florida 34243

USA

SRN: US-MF-000008811

For production and final product inspection/testing of:

topical hydrophilic dressings for temporary bleeding control associated with minor and surgical wounds

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, 22 October 2025



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

Menaka Singh
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

MDR-CO-078-B V0.6

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	2843296	22.10.2025

Products covered by this Certificate:

Product Description	Product Name	Class
083406100POWDER7C	StatSeal Powder: LP007/StatSeal Advanced - 1 Application LP607/StatSeal Advanced - Box of 6 Applications LP637/StatSeal Advanced - Case of 24 Applications LP006/StatSeal - 1 Application LP606/StatSeal - Box of 6 Applications LP636/StatSeal - Case of 24 Applications StatSeal Disc: DA018/StatSeal Advanced - 1 Application DA618/StatSeal Advanced - Box of 6 Applications DA628/StatSeal Advanced - Case of 24 Applications DL016/StatSeal Large - 1 Application DL616/StatSeal Large - Box of 6 Applications DL626/StatSeal Large - Case of 24 Applications DM015/StatSeal Medium - 1 Application DM615/StatSeal Medium - Box of 6 Applications DM625/StatSeal Medium - Case of 24 Applications DS014/StatSeal Small - 1 Application DS614/StatSeal Small - Box of 6 Applications DS624/StatSeal Small - Case of 24 Applications DX017/StatSeal Extra Large - 1 Application DX617/StatSeal Extra Large - Box of 6 Applications DX627/StatSeal Extra Large - Case of 24 Applications DAP019/StatSeal Advanced Plus - 1 Application DAP619/StatSeal Advanced Plus - Box of 6 Applications DAP629/StatSeal Advanced Plus - Case of 24 Applications DAR020/StatSeal Advanced RAD - 1 Application DAR620/StatSeal Advanced RAD - Box of 6 Applications DAR630/StatSeal Advanced RAD - Case of 24 Applications	Ila

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Biolife, L.L.C.	8163 25 th Court East, Sarasota, Florida 34243, USA

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.