DNV·GL

# EC CERTIFICATE

## Production Quality Assurance

| Certificate No.: | Project No.: | Valid Until: |
|---|---|---|
| 10000370966-PA-NA-DNK Rev 1.0 | PRJN-188795-2020-PA-DNK | 25 January 2024 |

This is to certify that the quality system of:

## Biolife, L.L.C

8163 25th Court East
Sarasota, FL 34243
USA

For production and final product inspection/testing of:
**Manufacture and final inspection of topical hydrophilic dressings for temporary bleeding control associated with minor (cuts, lacerations, skin tears, anterior nosebleeds, vascular access), and surgical wounds.**

Has been assessed with respect to:
**The conformity assessment procedure described in Annex V of Council Directive 93/42/EEC on Medical Devices, as amended**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
**Høvik, 17 August 2020**

NORWEGIAN ACCREDITATION

**PROD 021**

For:
**DNV GL PRESAFE AS**

**Notified Body No.: 2460**

Eugenie Winger Husebye

**Eugenie Winger Husebye**

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

**Jurisdiction**

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

| Revision | Description | Issue Date |
|---|---|---|
| 0.0 | Transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM -920 to DNV GL Presafe A/S (NB2460) | 18 June 2020 |
| 1.0 | Admin changes and removal of product | 17 August 2020 |

Products covered by this Certificate:

| Product Description | Product Name | Class |
|---|---|---|
| StatSeal Powder | LP007<br>LP607<br>LP637<br>LP006<br>LP606<br>LP636 | IIa |
| StatSeal Disc | DA018<br>DA618<br>DA628<br>DL016<br>DL616<br>DL626<br>DM015<br>DM615<br>DM625<br>DS014<br>DS614<br>DS624<br>DT013<br>DT613<br>DT623<br>DX017<br>DX617<br>DX627<br>DAP019<br>DAP619<br>DAP629<br>DAR020 | IIa |

| | | |
|---|---|---|
| | DAR620<br>DAR630 | |

The complete list of devices is filed with the Notified Body

**Sites covered by this certificate**

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

**EU Representative**
Emergo-Europe, Prinsessegracht 20, 2514 AP, The Hague, 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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate