EC Certificate

Certificate Number: DGM – 717

This is to certify that the quality system of:

Biolife, L.L.C.
8163 25th Court East
Sarasota, FL 34243
USA

has been approved in conformity with the requirements of

Annex V, section 3.2 - Production quality assurance

of Council Directive 93/42/EEC concerning medical devices as transposed into Danish law.

The certificate covers the following activities:

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 in class IIa

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. This EC certificate is issued pursuant to the Presafe Denmark A/S terms and conditions for the certification of medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits as per the Directive.

Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue:	2015-10-23
Expires:	2018-12-01
Initial date of issue:	2010-12-01
Reference:	aur5a1309v90f743

Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark

The following product families in class IIa are covered by the certificate:

WoundSeal Pour Pack

WoundSeal + Applicator

StatSeal Advanced

StatSeal

StatSeal Disc

The authorized EC representative:

Emergo-Europe

Molenstraat 15

2513 BH The Hague

The Netherlands

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