Presafe®
A DNV GL COMPANY

Quality System Certificate

DANAK
SYSTEM Reg. No. 5007

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 845	Aur1i2010v110f826	2021-02-02	2024-02-02	2014-09-30

This is to certify that the quality system of:

Vitrolife Sweden AB
Gustaf Werners Gata 2
SE-421 32 Västra Frölunda (visiting address)
Box 9080, SE-400 92 Göteborg (postal address)

fulfills the requirements in:

EN ISO 13485:2016

The certificate covers the following activities:

Development, manufacture and marketing of products and systems for preparation, cultivation and storage of cells, intended for therapy

The 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. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2003, DS/EN ISO 13485:2016, EN ISO 13485:2016, ISO 13485:2016, DS/EN ISO 9001: 2015, EN ISO 9001:2015, and ISO 9001:2015 include the requirements of any applicable corrigendum. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

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

Heidi Jørgensen

For Presafe Denmark A/S