Presafe®
A DNV GL COMPANY

Quality System Certificate

DANAK
SYSTEM Reg. No. 510

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 510	aur2a1910v801f119	2019-12-30	2022-12-30	2005-09-14

This is to certify that the quality system of:

ORIGIO a/s
Knardrupvej 2
2760 Måløv
Denmark

fulfills the requirements in:

DS/EN ISO 13485:2016

The certificate covers the following activities:

Design, development, manufacture, final testing and distribution of storage devices, cell culture products, needles and catheters for use in assisted reproductive technology (ART) procedures.

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
Authorized person

For Presafe Denmark A/S