



Quality System Certificate

Certificate Number: DGM – 510

This is to certify that the quality system of:

ORIGIO a/s
Knardrupvej 2
2760 Måløv
Denmark

fulfills the requirements in:

DS/EN ISO 13485:2012

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.

Design, development, manufacture, final testing and distribution of storage devices, 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 9001: 2008, EN ISO 9001:2008 and ISO 9001:2008 include the requirements of the applicable corrigenda. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.


Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue: 2017-12-28
Expires: 2019-02-28
Initial date of issue: 2005-09-14
Reference: aur2a1712v660f119

Presafe Denmark A/S

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