EC Design Examination Certificate

Certificate Number: DGM – 813

This is to certify that the defined representative samples of the device manufactured by:

ORIGIO a/s
Knardrupvej 2
2760 Måløv
Denmark

have been approved in conformity with the requirements of

Annex II Section 4 - Examination of the design of the product

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

The certificate covers the following devices:

Cell culture products for in-vitro fertilization in class III

The Design Examination certificate is valid provided that no substantial changes are made to the approved design that could affect conformity with the essential requirements or the conditions prescribed for use for the product without the approval of Presafe Denmark A/S. The EC-Design Examination certificate is issued in accordance with Presafe Denmark A/S' terms and conditions cf. Council Directive 93/42/EEC concerning medical devices as transposed into Danish law. The certificate is based on successful evaluation of the device design.

Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue:	2013-12-09
Expires:	2018-12-09
Initial date of issue:	2013-12-09
Reference:	Art2a1308v193f119

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

The following products in class III are covered by the certificate:

- **ORIGIO® Sequential Fert™ (8301, 8302)**
- **ORIGIO® Sequential Cleav™ (8303, 8304)**
- **ORIGIO® Sequential Blast™ (8305, 8306)**

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