



# EC Design Examination Certificate

Certificate Number: DGM – 633

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 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

Information on electronic signature [www.presafe.com](http://www.presafe.com)

Date of issue: 2018-03-13  
Expires: 2023-03-13  
Initial date of issue: 2008-03-17  
Reference: Art2a1801v681f119



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

**DGM**

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

(Incl. HAS)

- Sperm Preparation Medium (10691010X\*, 10690060X\*, 10695060X\*, 10702010X\*, 10701010X\*, 10700060X\*, 10705060X\*)
- UTM<sup>™</sup> Transfer Medium (10520010X\*, 11520010X\*)
- PVP Medium (10890001X\*)
- PVP Clinical Grade (10905000X\*)
- SpermSlow<sup>™</sup> (10944000X\*)
- Sperm Freezing Medium (10670010X\*)
- Embryo Freezing Pack (10264010X\*, 10264002X\*)
- BlastFreeze<sup>™</sup> (10532010X\*, 10534002X\*)
- BlastThaw<sup>™</sup> (10542010X\*, 10544002X\*)
- Flushing Medium (10765060X\*, 10760125X\*, 10845060X\*, 10840125X\*)
- Universal IVF Medium (10301010X\*, 10300060X\*, 10305060X\*, 10311010X\*, 10310060X\*, 10315060X\*)
- Medicult IVM<sup>®</sup> System (82214010X\*)
- SupraSperm<sup>®</sup> System (10922010X\*, 10922060X\*)
- Biopsy Medium (10620010X\*)
- Embryo Thawing Pack (10984010X\*, 10984002X\*)
- ICSI Cumulase<sup>®</sup> (16125000X\*)

(Ex. HAS)

- SynVitro<sup>®</sup> Flush (15760125X\*, 15840125X\*)
- CryoSperm<sup>™</sup> (11010010X\*)

(\*X=country code)

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