



# EC Design Examination Certificate

## Directive 93/42/EEC on Medical Devices, Annex II, section 4

Certificate No.:  
**DGM – 871**

Reference:  
**Art2a2001v851f119**

Date of issue:  
**2020-05-18**

Valid Until:  
**2024-05-26**

Initial date of issue:  
**2016-09-05**

This is to certify that the design dossier relating to the devices 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 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' "General terms and conditions" cf. Council Directive 93/42/EEC concerning medical devices. The certificate is based on successful evaluation of the device design dossier in accordance with the MDD, Annex II, section 4.

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

  
**Heidi Jørgensen**  
Authorized person  
For Presafe Denmark A/S



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

<b>Product Identifier</b>	<b>Product name</b>	<b>GMDN code</b>
84051010X*	Origio Sperm Wash	44046
84050060X*	Origio Sperm Wash	44046
84055060X*	Origio Sperm Wash	44046

\*X=country code