EC Design Examination Certificate

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

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 822	art2a1902v741f119	2019-05-10	2024-05-10	2014-07-03

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

Henrik Grønborg Larsen
Authorized person
For Presafe Denmark A/S

EC Design Examination Certificate

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

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 822	art2a1902v741f119	2019-05-10	2024-05-10	2014-07-03

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

Product Identifier	Product name	GMDN code
67010010X*	SAGE 1-Step	44046
67010060X*	SAGE 1-Step	44046

(*X = Country code)