



EC Design Examination Certificate

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

Certificate No.:
DGM – 633

Reference:
Art2a2002v880f119

Date of issue:
2020-05-18

Valid Until:
2023-03-13

Initial date of issue:
2008-03-17

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:

Product Identifier	Product name	GMDN code
10691010X*	Sperm Preparation Medium	44046
10690060X*	Sperm Preparation Medium	44046
10695060X*	Sperm Preparation Medium	44046
10700010X*	Sperm Preparation Medium	44046
10702010X*	Sperm Preparation Medium	44046
10701010X*	Sperm Preparation Medium	44046
10700060X*	Sperm Preparation Medium	44046
10705060X*	Sperm Preparation Medium	44046
10520010X*	UTM™ Transfer Medium	44046
11520010X*	UTM™ Transfer Medium	44046
10890001X*	PVP Medium	44046
10900000X*	PVP Clinical Grade	44046
10905000X*	PVP Clinical Grade	44046
10940000X*	SpermSlow™	44046
10944000X*	SpermSlow™	44046
10670010X*	Sperm Freezing Medium	44046
10264010X*	Embryo Freezing Pack	42850
10264002X*	Embryo Freezing Pack	42850
10532010X*	BlastFreeze™	42850
10534002X*	BlastFreeze™	42850
10542010X*	BlastThaw™	42850
10544002X*	BlastThaw™	42850
10765060X*	Flushing Medium	44046
10760125X*	Flushing Medium	44046
10840060X*	Flushing Medium	44046
10845060X*	Flushing Medium	44046
10840125X*	Flushing Medium	44046



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Product Identifier	Product name	GMDN code
10301010X*	Universal IVF Medium	44046
10300060X*	Universal IVF Medium	44046
10305060X*	Universal IVF Medium	44046
10310010X*	Universal IVF Medium	44046
10311010X*	Universal IVF Medium	44046
10310060X*	Universal IVF Medium	44046
10315060X*	Universal IVF Medium	44046
82214010X*	Medicult IVM® System	42850
10922010X*	SupraSperm® System	42850
10922060X*	SupraSperm® System	42850
10620010X*	Biopsy Medium	44046
10984010X*	Embryo Thawing Pack	42850
10984002X*	Embryo Thawing Pack	42850
16120000X*	ICSI Cumulase®	44046
16125000X*	ICSI Cumulase®	44046
Ex. HAS		
15760125X*	SynVibro® Flush	44046
15840125X*	SynVibro® Flush	44046
11010010X*	CryoSperm	44046