



EC Certificate

Full Quality Assurance System

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

Certificate No.:
DGM – 555

Reference:
Aur2a1901v730f119

Date of issue:
2019-04-03

Valid Until:
2022-01-31

Initial date of issue:
2008-03-17

This is to certify that the quality system of:

ORIGIO a/s
Knardrupvej 2
2760 Måløv
Denmark

has been audited under the requirements of:

Annex II, Full quality assurance system, excluding section 4, of Council Directive 93/42/EEC as transposed into Danish law. The quality system meets the requirements of the MDD, Annex II. For the placing on the market of class III products covered by this certificate an Annex II section 4 certificate is required.

The certificate covers the following devices:

Design, development, manufacture and final testing of storage devices, cell culture products, needles and catheters for use in assisted reproductive technology (ART) procedures in class III, IIb, IIa and I

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the manufacturer does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. This EC certificate is issued in accordance with Presafe Denmark A/S' "General terms and conditions" cf. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the MDD, Annex II, section 5

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 product(s) in class III are covered by the certificate and by the EC Design Examination Certificate DGM –633:

Product Identifier	Product name	GMDN code
10691010X*	Sperm Preparation Medium	44046
10690060X*	Sperm Preparation Medium	44046
10695060X*	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
10905000X*	PVP Clinical Grade	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
10845060X*	Flushing Medium	44046
10840125X*	Flushing Medium	44046
10301010X*	Universal IVF Medium	44046
10300060X*	Universal IVF Medium	44046
10305060X*	Universal IVF Medium	44046



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Product Identifier	Product name	GMDN code
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
16125000X*	ICSI Cumulase®	44046

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15760125X*	SynVitto® Flush	44046
15840125X*	SynVitto® Flush	44046
11010010X*	CryoSperm	44046

The following product(s) in class III are covered by the certificate and by the EC Design Examination Certificate DGM –723:

Product Identifier	Product name	GMDN code
12284001X*	MediCult Vitrification Cooling	42850
12295002X*	MediCult Vitrification Warming	42850



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The following product(s) in class III are covered by the certificate and by the EC Design Examination Certificate DGM –813:

Product Identifier	Product name	GMDN code
83010010X*	Origio® Sequential Fert™	44046
83010060X*	Origio® Sequential Fert™	44046
83020010X*	Origio® Sequential Fert™	44046
83020060X*	Origio® Sequential Fert™	44046
83030010X*	Origio® Sequential Cleav™	44046
83030060X*	Origio® Sequential Cleav™	44046
83040010X*	Origio® Sequential Cleav™	44046
83040060X*	Origio® Sequential Cleav™	44046
83050010X*	Origio® Sequential Blast™	44046
83050060X*	Origio® Sequential Blast™	44046
83060010X*	Origio® Sequential Blast™	44046
83060060X*	Origio® Sequential Blast™	44046

The following product(s) in class III are covered by the certificate and by the EC Design Examination Certificate DGM –822:

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

The following product(s) in class III are covered by the certificate and by the EC Design Examination Certificate DGM –827:

Product Identifier	Product name	GMDN code
12040003X*	EmbryoGen®	44046



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The following product(s) in class III are covered by the certificate and by the EC Design Examination Certificate DGM –857:

Product Identifier	Product name	GMDN code
12050003X*	BlastGen®	44046

The following product(s) in class III are covered by the certificate and by the EC Design Examination Certificate DGM –871:

Product Identifier	Product name	GMDN code
84051010X*	ORIGIO® Sperm Wash	44046
84050060X*	ORIGIO® Sperm Wash	44046
84055060X*	ORIGIO® Sperm Wash	44046

The following product(s) in class III are covered by the certificate and by the EC Design Examination Certificate DGM –892:

Product Identifier	Product name	GMDN code
84010060X*	ORIGIO® Gradient™ 90	44046
84022060X*	ORIGIO® Gradient™ 40/80	42850
84022010X*	ORIGIO® Gradient™ 40/80	42850
84021210X*	ORIGIO® Gradient™ 40/80	42850



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The following product families in class IIb are covered by the certificate:

Product	GMDN code
SupraSperm® 100 (10970060X, 10970500X, 10972060X)	42850
Origio® Gradient™ 100 (84000060X, 84002060X, 84004125X)	44046

The following product families in class IIa are covered by the certificate

Product	GMDN code
McGill Cryoleaf™ (40770000X*, 40771401X*)	47446
VitriFit® (42782001X*, 42785005X*, 42792001X*, 42795005X*, 42802001X*, 42805005X*, 42812001X*, 42815005X*, 42822001X*, 42825005X*, 42842001X*, 42845005X*, 42852001X*, 42855005X*, 42862001X*, 42865005X*)	47446
Acidified Tyrodes Solution (10605000X*)	44046
Liquid Paraffin (10100060X*, 10100500X*, 10105060X*)	44046
Follicle aspiration Set	
Oocyte Retrieval Needles:	45676
-Oocyte RS	
-Oocyte RSS	
-Oocyte RD	



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The following product families in class Is are covered by the certificate:

Product	GMDN code
Insemination Catheters	45846
-INCA IUI	
Embryo Transfer Catheters	45846
-Transem Soft	
-Transem Support	
-Transem Angled	
-Transem Angled O (with obturator)	
-Transem Trial	
-Transem Stylet	
-Transem Spherical	
-Transem Spherical (with obturator)	
-EchoGen Soft	
-EchoGen Support	
-EchoGen Angled	
-EchoGen Angled O (with obturator)	
-EchoGen/Spherical	
-EchoGen/Spherical O (with obturator)	
VTS Vacuum Tube Set	45846

(*X=country code)