

This is to certify that the quality system of:

ORIGIO a/s
Knardrupvej 2
2760 Måløv
Denmark

has been approved in conformity with the requirements of:

Annex II Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as ammended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

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 Is

This EC certificate is issued in accordance with Presafe Denmark A/S' 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 Directive.



Carsten Worm Jensen
Authorized person

For Presafe Denmark A/S

Date of issue: 2017-01-31
Expires: 2022-01-31
Initial date of issue: 2008-03-17
Reference: aur2a1701v620f119

The following products in class III are covered by the certificate and by the EC Design Examination Certificates DGM – 633, DGM – 723, DGM – 813, DGM-822, DGM-827, DGM-857 and DGM-871

(Incl. HAS)

- Sperm Preparation Medium (1069, 1070)
- EmbryoAssist™ (1214, 1213)
- ISM1™ Culture Medium (1050, 1150)
- UTM™ Transfer Medium (1052, 1152)
- PVP Medium 1089
- PVP Clinical Grade 1090
- SpermSlow™ 1094
- Sperm Freezing Medium 1067
- Embryo Freezing Pack 1026
- BlastFreeze™ 1053
- BlastThaw™ 1054
- Flushing Medium (1076, 1084)
- BlastAssist® (1215, 1216)
- Universal IVF Medium (1030,1031)
- Medicult IVM® System (8221)
- SupraSperm® System (1092)
- Biopsy Medium (1062)
- Embryo Thawing Pack (1098)
- ICSI Cumulase® (1612)
- MediCult Vitrification Cooling (12284001X*)
- MediCult Vitrification Warming (12295002X*)
- ORIGIO® Sequential Fert™ (8301, 8302)
- ORIGIO® Sequential Cleav™ (8303, 8304)
- ORIGIO® Sequential Blast™ (8305, 8306)
- SAGE 1-Step™ (6701)
- EmbryoGen® (1204)
- BlastGen™ (1205)
- ORIGIO Sperm Wash (84051010X*, 84050060X*, 84055060X*)

(*X=country code)

Certificate number: DGM – 555
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(Ex. HAS)

- **SynVibro®Flush (1576, 1584)**
- **CryoSperm™ (1101)**

The following product in class IIb is covered by the certificate:

- **SupraSperm®100 (1097)**
- **Origio® Gradient™ 100 (8400)**

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

- **McGill Cryoleaf™ (4077)**
- **VitriFit™ (42782001X, 42792001X, 42802001X, 42812001X*)**
- **Acidified Tyrodes Solution (1060)**
- **Liquid Paraffin (1010)**
- **Follicle aspiration Set**

Oocyte Retrieval Needles:

- Oocyte RS
- Oocyte RSS
- Oocyte RD

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

Insemination Catheters

- INCA IUI

Embryo Transfer Catheters

- Transem Soft
- Transem Support
- Transem Angled
- Transem Angled O (with obturator)
- Transem Trial
- Transem Stylet
- Transem Spherical

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- Transem Spherical (with obturator)
- EchoGen Soft
- EchoGen Support
- EchoGen Angled
- EchoGen Angled O (with obturator)

VTS Vacuum Tube Set

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