

EC Certificate

DGM-555

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, section 3.2 - Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law.

The scope of the certification is:

**Design, development, manufacture and final testing of storage devices
and cell culture products for in-vitro fertilization in class III, IIb and IIa**

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of DS Certificering A/S. This EC certificate is issued pursuant to the DS Certificering A/S rules for the certification of medical devices and entitles the certificate holder to affix the CE mark.



Nina Christensen
Authorized person

Valid from: 2011-05-24
Valid until: 2016-05-24
Initial date of issue: 2008-03-17
Reference: Aur2a1101v320f119

DS Certificering A/S

Notified Body, Identification No. 0543
Kollegievej 6, DK-2920 Charlottenlund, Denmark

The following products in class III are covered by the certificate
and by the EC Design Examination Certificates DGM-633 and DGM-723:

(Incl. HAS)

- **Sperm Preparation Medium (1069, 1070)**
- **EmbryoAssist™(1214, 1213)**
- **ISM1™ Culture Medium (1050, 1150)**
- **ISM2™ Culture Medium (1051, 1151)**
- **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)**

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- **Biopsy Medium (1062)**
- **Embryo Thawing Pack (1098)**
- **ICSI Cumulase® (1612)**
- **MediCult Vitrification Cooling (1228)**
- **MediCult Vitrification Warming (1229)**

(Ex. HAS)

- **SynVibro®Flush (1576, 1584)**
- **SynVibro® ICSI Holding Medium™ (1585)**
- **CryoSperm™ (1101)**

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

- **SupraSperm®100 (1097)**

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

- **McGill Cryoleaf™ (4077)**
- **Acidified Tyrodes Solution (1060)**

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