

EC Design-Examination Certificate

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

No. CE 551319
Issued To: **CooperSurgical Inc.,**
also trading as
SAGE In-Vitro Fertilization
95 Corporate Drive
Trumbull
Connecticut
06611
USA

In respect of:

**In-Vitro Fertilization media incorporating Human Serum Albumin and /or gentamicin sulphate
for use in assisted reproduction processes**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **11 March 2011**

Date: **08 March 2016**

Expiry Date: **10 March 2021**

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IVF Media incorporating HSA and antibiotic

Ref Number	Name of Medical Device	Components
ART-1005	Quinn's® Sperm Wash Kit	ART-1005-12 Quinn's® Sperm Wash, 12 x 12 mL
ART-1006	Quinn's® Sperm Wash, 100 mL	NA
ART-1520	Quinn's Advantage® Protein Plus Fertilization (HTF) Medium, 1 x 20 mL	NA
ART-2004	PureCeption®, 4 determination Kit	ART-2005-12 Sperm Washing Medium, 1 x 12 mL ART-2040-12 PureCeption® 40% Upper Phase, 1 x 12 mL ART-2080-12 PureCeption® 80% Lower Phase, 1 x 12 mL
ART-2016	PureCeption®, 16 determination Kit	ART-2005-12 Sperm Washing Medium, 4 x 12 mL ART-2040-12 PureCeption® 40% Upper Phase, 4 x 12 mL ART-2080-12 PureCeption® 80% Lower Phase, 4 x 12 mL
ART-4005-A	PVP, 7% Ready to Use Solution Kit	ART-4005 PVP, 7% Ready to Use Solution, 6 x 0.5 mL
ART-4006-A	PVP, 10% Ready to Use Solution Kit	ART-4006 PVP, 10% Ready to Use Solution, 6 x 0.5 mL

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Ref Number	Name of Medical Device	Components
ART-8014	Quinn's Advantage® Embryo Freezing Kit	ART-8001-12 1.5M Propanediol 0.1M Sucrose Freezing Medium 2 x 12 mL ART-8003-12 1.5M Propanediol Freezing Medium, 2 x 12 mL ART-8013-12 Cryokit Diluent 1 x 12 mL
ART-8015	Quinn's Advantage® Blastocyst Freezing Kit	ART-8009-12 5% Glycerol Freezing Medium, 1 x 12 mL ART-8011-12 9% Glycerol, 0.2 M Sucrose Freezing Medium, 1 x 12 mL ART-8013-12 Cryokit Diluent, 1 x 12 mL
ART-8016	Quinn's Advantage® Thawing Kit	ART-8005-12 0.5M Sucrose Thawing Medium, 1 x 12 mL ART-8007-12 0.2M Sucrose Thawing Medium, 1 x 12 mL ART-8013-12 Cryokit Diluent, 1 x 12 mL
ART-8017	CSC Freezing Medium Kit	ART-8017-A CSC Freezing Medium, 1 x 10 mL
ART-8018	CSC Thawing Medium Kit	ART-8018-A 0.5M Sucrose CSC Thawing Medium ART-8018-B 0.2M Sucrose CSC Thawing Medium ART-8018-C CSC Washing Medium with HEPES
ART-8022	Quinn's Advantage® Sperm Freezing Medium Kit	ART-8020-12 Quinn's Advantage® Sperm Freezing Medium 6 x 12 mL

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Ref Number	Name of Medical Device	Components
ART-8025	Vitrification Kit	ART-8025-A Equilibration Solution, 1 x 2 mL ART-8025-B Vitrification Solution, 1 x 2 mL
ART-8030	Vitrification Warming Kit	ART-8030-A 1.0M Sucrose Warming Solution, 1 x 4 mL ART-8030-B 0.5M Sucrose Warming Solution, 1 x 2 mL ART-8030C MOPS Solution, 1 x 6 mL

IVF Media incorporating HSA

Ref Number	Name of Medical Device	Components
ART-1012	Quinn's® Sperm Wash Kit (without antibiotic)	ART-1012-12 Quinn's® Sperm Wash without antibiotic 12 x 12 mL

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Human Serum Albumin for supplementation of IVF Media product codes ART-1020 & ART-1021

Ref Number	Name of Medical Device	Components
ART-3001	Human Albumin Solution 100mg/mL	ART-3001-5 Human Serum Albumin, 12 x 5 mL
ART-3003	Human Albumin Solution 100mg/mL 100mL	NA

IVF Media incorporating antibiotic, without HSA

Ref Number	Name of Medical Device	Components
ART-1020	Quinn's Advantage® Fertilization (HTF) Medium, 50 mL	NA
ART-1021	Quinn's Advantage® Fertilization (HTF) Medium, 100 mL	NA
ART-1023	Quinn's Advantage® Medium with HEPES, 100 mL	NA
ART-1024	Quinn's Advantage® Medium with HEPES, 500 mL	NA

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IVF Media incorporating antibiotic, without HSA (continued)

Ref Number	Name of Medical Device	Components
ART-1026	Quinn's Advantage® Cleavage Medium, 50 mL	NA
ART-1027	Quinn's Advantage® Cleavage Medium, 100 mL	NA
ART-1029	Quinn's Advantage® Blastocyst Medium	NA
ART-2024	PureCeption® 24 determination kit	ART-2040-12 PureCeption® 40% Upper Phase, 6 x 12 mL ART-2080-12 PureCeption® 80% Lower Phase, 6 x 12 mL
ART-2040	PureCeption® 40% Upper Phase	NA
ART-2080	PureCeption® 80% Lower Phase	NA
ART-2100	PureCeption® 100% Isotonic	NA
ART-4100	Quinn's Advantage® Medium with HEPES (Ca/Mg Free) Kit	ART-4100-12 Quinn's Advantage® Medium with HEPES (Ca/Mg Free) 4 x 12 mL

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Certificate History

Date	Reference Number	Action
11 March 2011	10122914	First Issue.
22 September 2011	10130495	Addition of product codes ART-3001 & ART-3003, Human Albumin solution for the supplementation of IVF Media product codes ART-1020 & ART-1021.
11 November 2015	10146088	Transfer of manufacturing from Sage In Vitro Fertilization, Inc (Pasadena) to Origio a/s (Denmark). Removal of part number ART-1600 and ART-4013-A. Administrative changes to Ref. Numbers.
29 January 2016	10160232	Addition of product code ART-4006-A.
08 March 2016	10161620	Certificate renewal.

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