

Certificate

Design Examination

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

On the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 4.

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

Rob Wallis, Chair Certification Body Management Committee

First Issued: 11 Mar 2011

Date: 22 Sep 2011

Expiration Date: 10 Mar 2016

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.

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Supplementary Information to CE 551319

Issued to:
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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-1600	In Vitro Maturation Kit	ART-1600-A Oocyte Washing Medium, 1 x 50 mL ART-1600-B Oocyte Maturation Medium, 1 x 20 mL ART-1600-C Embryo Maintenance Medium, 1 x 5 mL
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% Upper 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% Upper 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

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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	Virtrification 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-80-C 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 100mL	12 x 5 mL
ART-3003	Human Albumin Solution 100mg/mL 100mL	100mL

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® Blasocyst 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-4013-A	Acidified Medium, Kit	ART-4013 Acidified Medium, 6 x 1 mL
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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History of Certificate

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

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