

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2011-03-11**

Date: **2019-02-19**

Expiry Date: **2021-03-10**

...making excellence a habit.™

Page 1 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 551319

Issued To: **CooperSurgical Inc.,
also trading as
SAGE In-Vitro Fertilization
95 Corporate Drive
Trumbull
Connecticut
06611
USA**

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

First Issued: **2011-03-11**

Date: **2019-02-19**

Expiry Date: **2021-03-10**

...making excellence a habit.™

Page 2 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 551319

Issued To:

**CooperSurgical Inc.,
also trading as
SAGE In-Vitro Fertilization
95 Corporate Drive
Trumbull
Connecticut
06611
USA**

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

First Issued: **2011-03-11**

Date: **2019-02-19**

Expiry Date: **2021-03-10**

...making excellence a habit.™

Page 3 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.



EC Design-Examination Certificate

Supplementary Information to CE 551319

Issued To:

**CooperSurgical Inc.,
also trading as
SAGE In-Vitro Fertilization
95 Corporate Drive
Trumbull
Connecticut
06611
USA**

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

First Issued: **2011-03-11**

Date: **2019-02-19**

Expiry Date: **2021-03-10**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 551319

Issued To:

**CooperSurgical Inc.,
also trading as
SAGE In-Vitro Fertilization
95 Corporate Drive
Trumbull
Connecticut
06611
USA**

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

First Issued: **2011-03-11**

Date: **2019-02-19**

Expiry Date: **2021-03-10**

...making excellence a habit.™

Page 5 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 551319

Issued To: **CooperSurgical Inc.,
also trading as
SAGE In-Vitro Fertilization
95 Corporate Drive
Trumbull
Connecticut
06611
USA**

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

First Issued: **2011-03-11**

Date: **2019-02-19**

Expiry Date: **2021-03-10**

...making excellence a habit.™

Page 6 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 551319

Issued To:

**CooperSurgical Inc.,
also trading as
SAGE In-Vitro Fertilization
95 Corporate Drive
Trumbull
Connecticut
06611
USA**

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.
Current	8660161	Traceable to NB 0086.

First Issued: **2011-03-11**

Date: **2019-02-19**

Expiry Date: **2021-03-10**

...making excellence a habit.™

Page 7 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

