

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 548538
Issued To: **Kitazato Corporation**
100-10 Yanagishima
Fuji
Shizuoka
416-0932
Japan

In respect of:

The manufacture of sterile cell freezing tool (Cryotop), sterile oocyte pickup needles and sterile plasticware used in Assisted Reproduction Techniques (ART). Those aspects relating to securing and maintaining sterility of embryo transfer catheters and intrauterine insemination catheters.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-09-28**

Date: **2021-04-26**

Expiry Date: **2024-05-26**

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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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

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Supplementary Information to CE 548538

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Number	Device Name	Intended purpose per IFU
Class IIa		
SMD 0109	Sterile cell freezing tool (Cryotop)	Used for storage of vitrified human oocytes and embryos.
SMD 0109	Sterile plasticware	Used for holding the solution/media when handling embryo or oocyte during vitrification/thawing, or when culturing embryo or oocyte during ART.
SMD 0109	OPU Needle	Used to puncture the human body and pick up tissue for examination, treatment and diagnosis.
Class Is		
SMD 0109	ET Catheter	Used to place sperm or embryos into the uterine cavity through the cervix.
SMD 0109	IUI Catheter	Used for introduction of washed spermatozoa into the uterine cavity through the cervix.

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