By Royal Charter

# 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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**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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