

EC Certificate - Full Quality Assurance System

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

No. CE 711840
Issued To: **Kitazato Corporation**
100-10 Yanagishima
Fuji
Shizuoka
416-0932
Japan

In respect of:

Design, development and manufacture of sterile media without ancillary medicinal substances for preparation, handling, washing and culture overlay of human gametes and embryos for use in Assisted Reproductive Technology (ART) procedures.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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: **2020-04-17**

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 711840

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Number	Device Name	Intended purpose per IFU
Class IIb		
MD0109	SepaSperm Solution	SepaSperm Solution is used for separation of motile sperm from seminal fluid with density gradient method.
MD0109	Gamete Buffer	Gamete Buffer is used for washing procedures and handling of human gametes and embryos outside the incubator, including ICSI, IUI and embryo transfer.
Class IIa		
MD0109	Hypure Oil Light Hypure Oil Heavy	Intended to be used as an overlay for culture of embryos, oocytes and sperm in ART and micromanipulation procedures.

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