

EC Certificate - Full Quality Assurance System

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

No. CE 563699
Issued To: **Kitazato Corporation**
100-10 Yanagishima
Shizuoka
Fuji
Shizuoka
416-0932
Japan

In respect of:

Design, manufacture and final inspection of sterile vitrification and thawing media with and without ancillary medicinal substances for In Vitro Fertilisation and assisted reproductive processes.

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: **2012-07-13**

Date: **2021-05-18**

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 563699

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Number	Device Name	Intended purpose per IFU
Class III		
---	VT601	See CE 563702
---	VT602	
---	VT601N	
---	VT602N	
Class IIb		
42850	VT801	For vitrification of oocytes (MII) and embryos
42850	VT802	For thawing of oocytes (MII) and embryos

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