

# EC Design-Examination Certificate

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

**No.** CE 563702  
**Issued To:** **Kitazato Corporation**  
**100-10 Yanagishima**  
**Shizuoka**  
**Fuji**  
**Shizuoka**  
**416-0932**  
**Japan**

In respect of:

**Sterile vitrification and thawing media with gentamicin sulfate for use in assisted reproductive 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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-09-05**

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 563702

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Catalogue Number	Device Name	Model, Type	Intended Purpose per IFU	Classification
91101	Vitrification media with gentamicin, with phenol red	VT601	Vitrification Media is used for vitrification of oocytes (MII) and embryos. Thawing Media is used for warming vitrified oocytes (MII) and embryos.	Class III
91121	Thawing media with gentamicin, with phenol red	VT602		Class III
91195	Vitrification media with gentamicin, without phenol red	VT601N		Class III
91196	Thawing media with gentamicin, without phenol red	VT602N		Class III

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## Certificate History

Date	Reference Number	Action
05 September 2019	9664638	First Issue.
31 March 2020	9719587	Minor amendment to correct clerical error in supplementary information page of certificate.
Current	3338854	<p>Manufacturer name change from 'Kitazato Corporation Shizuoka Office' to 'Kitazato Corporation'.</p> <p>Legal address change and manufacturing site relocation from '81 Nakajima, Fuji-City, Shizuoka, 416-0907, Japan' to '100-10 Yanagishima, Fuji, Shizuoka, 416-0932, Japan'.</p> <p>Removal of 'cryopreservation' from Intended Purpose column, for Vitrification Media.</p> <p>Administrative change to format of device schedule table (column order changed).</p>

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