

EC Certificate - Production Quality Assurance

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

No. CE 711778
Issued To: **Kitazato Corporation**
Shizuoka Office
81 Nakajima
Fuji-city
Shizuoka
416-0907
Japan

In respect of:

Manufacture of sterile micro tools used 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 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: **2020-04-17**

Date: **2020-06-26**

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 711778

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Shizuoka Office
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Number	Device Name	Intended Purpose per IFU
Class IIa		
MD0109	Micro tools	The Micro tools are used in Assisted Reproductive Technology (ART) procedures.

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

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