By Royal Charter

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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Supplementary Information to CE 711778

Issued To:

Kitazato Corporation
Shizuoka Office
81 Nakajima
Fuji-city
Shizuoka
416-0907
Japan

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

First Issued: **2020-04-17** Date: **2020-06-26** Expiry Date: **2024-05-26**

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