

EC Certificate - Production Quality Assurance

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

No. CE 554167
Issued To: **KITAZATO Medical Co., Ltd.**
Shibakoen Building
1-1-8 Shibadaimon,
Minato-ku,
Tokyo
105-0012
Japan

In respect of:

The manufacture of sterile oocyte pickup needle, embryo transfer catheter and intrauterine insemination catheter

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 0086):



Gary Fenton, Global Assurance Director

First Issued: **17 October 2009**

Date: **24 October 2014**

Expiry Date: **23 October 2019**

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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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Dibimed-Biomedical Supply, S.L. C/ Luis Buñuel 1 - Oficinas Pta. 4 46015 Valencia Spain	EU Representative
Radia Industry Co., Ltd 168 Ooyagi Takasaki Gunma 370-0072 Japan	Gamma Sterilization
Steri-Tech Co., Ltd 5-13-1 Hanasaki Kazo-shi Saitama-ken 347-0032 Japan	ETO Sterilization

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
17 October 2009	7447401	First issue
01 August 2014	8192583	Administrative correction of client name from "Kitazato" to "KITAZATO". Change of client address from 2-15-12 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan to Shibakoen Building, 1-1-8 Shibadaimon, Minato-ku, Tokyo 105-0012, Japan
24 October 2014	8225541	Addition of "sterile" to certificate scope. Addition of significant subcontractor Steri-Tech Co., Ltd. Certificate renewal

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