



By Royal Charter

EC Certificate - Production Quality Assurance

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

No.

CE 548538

Issued To:

**KITAZATO BioPharma Co., Ltd.
81 Nakajima
Fuji-city
Shizuoka
416-0907
Japan**

In respect of:

The manufacture of sterile cell freezing tool (Cryotop)

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: **28 September 2009**

Date: **24 September 2014**

Expiry Date: **27 September 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 Japan	Sterilization

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Certificate History

Certificate No: **CE 548538**
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Date	Reference Number	Action
28 September 2009	7341826	First issue.
24 September 2014	8225500	Certificate renewal. Addition of 'sterile' to scope.

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