Certificate

Full Quality Assurance

No. CE 563699

Issued to:

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

In respect of:

The design and manufacture of IVF media without ancillary medicinal substances

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **13 Jul 2012** Date: **13 Jul 2012**

Expiration Date: **12 Jul 2017**

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000

Certificate

List of Significant Subcontractors

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

Certificate No. **CE 563699**

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Fuji-city
Japan

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

Certificate

History of Quality Assurance Certificate

Certificate No: CE 563699
Issue Date: 13 Jul 2012
Issued to: KITAZATO BioPharma Co., Ltd.
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Date	Reference Number	Action
13 July 2012	7544484	First Issue

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