

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 640689
Issued To: **Biocoat Inc.**
211 Witmer Road
Horsham
Pennsylvania
19044
USA

In respect of:

Design, development and manufacture of sterile PICSI[®] Sperm Selection culture dish device for the selection and capture of mature sperm used in the treatment of infertile couples by Intracytoplasmic Sperm Injection (ICSI).

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Frank Lee, EMEA Compliance & Risk Director

First Issued: **30 September 2015**

Date: **30 September 2015**

Expiry Date: **29 September 2020**

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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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List of Significant Subcontractors

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

Certificate No: **CE 640689**
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Pennsylvania
19044
USA

Subcontractor:

Service(s) supplied

Biocoat Inc.
 205 Witmer Road
 Horsham
 Pennsylvania
 19044
 USA

**Complaints Handling
 Vigilance**

Emergo Europe
 Molenstraat 15
 2513 BH The Hague
 Netherlands

EU Representative

Synergy Health AST, LLC
 6750 East 46th Avenue Drive
 Suite 100
 Denver
 Colorado 80216
 USA

E beam Sterilization

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 640689**
 Date: **30 September 2015**
 Issued To: **Biocoat Inc.
 211 Witmer Road
 Horsham
 Pennsylvania
 19044
 USA**

Date	Reference Number	Action
30 September 2015	8409727	Transfer of certificate No. US07/809 from SGS to BSI

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