

EC Certificate - Full Quality Assurance System

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

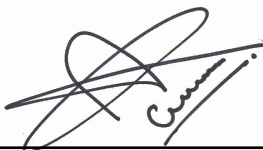
No. CE 640689
Issued To: **Biocoat Inc.**
211 Witmer Road
Horsham
Pennsylvania
19044
USA

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2015-09-30**

Date: **2019-02-27**

Expiry Date: **2023-02-19**

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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, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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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211 Witmer Road
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19044
USA

Subcontractor:	Service(s) supplied
Biocoat Inc. 123 Rock Road Horsham Pennsylvania 19044 USA	Regulatory Compliance
Emergo Europe Prinsessegracht 20 2514 AP The Hague The 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: **2019-02-27**
 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
16 February 2018	8848422	Certificate Renewal. EU rep address change, from 'Molenstraat 15 2513 BH, The Hague Netherlands' to – 'Emergo Europe, Prinsessegracht 20, 2514 AP The Hague The Netherlands'. Removal of Biocoat Inc, 205 Wilmer Road and addition of Biocoat Inc, 123 Rock Road.
Current	9719692	Traceable to NB 0086.

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