

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

Biocoat Inc.
211 Witmer Road
Horsham
Pennsylvania
19044
USA

Holds Certificate Number: MD 640691

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Design, development, manufacturing and distribution of sterile sperm selection medical device, in vitro diagnostic device for sperm analysis and medical grade liquid coatings for medical device applications.

For and on behalf of BSI:



Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 24/09/2015

Latest Revision Date: 04/02/2016

Effective Date: 20/02/2016

Expiry Date: 19/02/2019

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Certificate No: MD 640691

Location	Registered Activities
Biocoat Inc. 211 Witmer Road Horsham Pennsylvania 19044 USA	Design, development, manufacturing and distribution of sterile sperm selection medical device, in vitro diagnostic device for sperm analysis and medical grade liquid coatings for medical device applications.
Biocoat Inc. 215 Witmer Road Horsham Pennsylvania 19044 USA	Manufacture of medical grade liquid coatings for medical device applications
Biocoat Inc. 205 Witmer Road Horsham Pennsylvania 19044 USA	Complaints handling, PMS, Vigilance



Original Registration Date: 24/09/2015

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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