

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

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 13485:2016 & EN ISO 13485:2016 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 surface coatings for medical device applications.

The provision of contract coating services for medical devices.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-09-24

Latest Revision Date: 2019-08-27

Effective Date: 2019-02-20

Expiry Date: 2022-02-19

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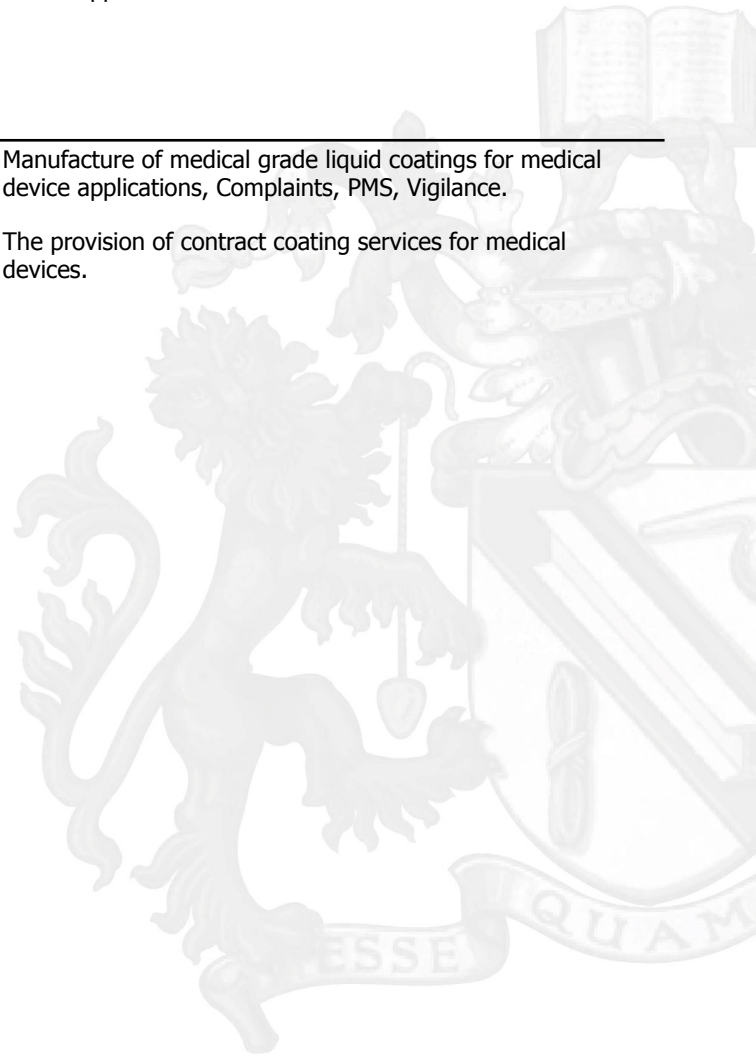


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...making excellence a habit.™

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 surface 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. 123 Rock Road Horsham Pennsylvania 19044 USA	Manufacture of medical grade liquid coatings for medical device applications, Complaints, PMS, Vigilance. The provision of contract coating services for medical devices.



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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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