

# Certificate of Registration

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

This is to certify that:

BBI Solutions OEM Ltd  
Unit 2, Parkway  
Pen-y-fan Industrial Estate  
Crumlin  
NP11 3EF  
United Kingdom

Holds Certificate Number:

**MD 674256**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Contract design, development and manufacture of gold colloid and lateral flow-based in-vitro diagnostic medical devices. Design, manufacture and supply of biological reagents and lateral flow test kits. Manufacture of immunological reagents, enzymes and related biochemicals. The design, development, manufacture and supply of in-vitro diagnostic reagents, blood and plasma products. The design and development of software for use in mobile diagnostics and monitoring solutions. The design, manufacture and supply of in vitro diagnostic antibodies. The design and development, manufacture and distribution of raw materials and intermediates for use in IVD manufacturing.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-06-05

Latest Revision Date: 2022-06-14

Effective Date: 2021-12-05

Expiry Date: 2024-06-04



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...making excellence a habit.™

Certificate No: **MD 674256**

Location	Registered Activities
BBI Solutions OEM Ltd Unit 2 Parkway Pen-y-fan Industrial Estate Crumlin NP11 3EF United Kingdom	Contract design, development and manufacture of gold colloid and lateral flow-based in-vitro diagnostic medical devices. Design, manufacture and supply of biological reagents and lateral flow test kits. Manufacture of enzymes and related biochemicals.
BBI Solutions OEM Ltd Broadoak Enterprise Centre Broadoak Road Sittingbourne ME9 8AQ United Kingdom	The design, development, manufacture and supply of in-vitro diagnostic reagents, blood and plasma products.
BBI Solutions OEM Ltd Porton Science Park Incubator Centre Bybrook Road Porton Down Salisbury Wiltshire SP4 0BF United Kingdom	Manufacture of immunological reagents.
Novarum DX Ltd Exchange Place 2 5 Semple Street Edinburgh EH3 8BL United Kingdom	The design and development of software for use in mobile diagnostics and monitoring solutions.
BBI Solutions Ltd 19 Packer Avenue Epping Industria 2 Cape town Western Cape South Africa	Manufacture of enzymes and related biochemicals.

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

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Location

BBI Solutions  
(Formerly Maine Biotechnology Services)  
1037R Forest Avenue  
Portland  
Maine  
04103  
USA

Registered Activities

The design, manufacture and supply of in vitro diagnostic antibodies.

DIARECT GmbH (part of BBI Solutions)  
Bötzingen Straße 29B  
Freiburg  
79111  
Germany

The design and development, manufacture and distribution of raw materials and intermediates for use in IVD manufacturing.



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