

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, manufacture and supply of lateral flow devices, ELISA kits and reagents for in-vitro diagnostic use. Manufacture of biological reagents and consumables. Manufacture of immunological reagents. Manufacture of enzymes and related biochemicals. 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 Global Regulatory & Quality

Original Registration Date: 2018-06-05

Latest Revision Date: 2024-06-03

Effective Date: 2024-06-05

Expiry Date: 2027-06-04



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Location	Registered Activities
BBI Solutions OEM Ltd Unit 2 Parkway Pen-y-fan Industrial Estate Crumlin NP11 3EF United Kingdom	Contract design, development, manufacture and supply of lateral flow devices, ELISA kits and reagents for in-vitro diagnostic use. Manufacture of biological reagents and consumables.
BBI Solutions OEM Ltd Porton Science Park Incubator Centre Bybrook Road Porton Down Salisbury Wiltshire SP4 0BF United Kingdom	Manufacture of immunological reagents.
BBI Enzymes SA (Pty) Ltd (trading as BBI Solutions) 19 Packer Avenue Epping Industria 2 Cape Town Western Cape South Africa	Manufacture of enzymes and related biochemicals.
BBI Solutions (Formerly Maine Biotechnology Services) 1037R Forest Avenue Portland Maine 04103 USA	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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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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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