By Royal Charter

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

**Bion Enterprises, Ltd.**
455 State Street
Suite 100
Des Plaines
Illinois
60016
USA

Holds Certificate Number: FM 702773

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

Design, development, manufacture and distribution of in-vitro diagnostic reagents used in testing for autoimmune, degenerative, and infectious diseases determination.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2005-10-14
Latest Revision Date: 2025-11-20

Effective Date: 2025-12-05
Expiry Date: 2028-12-04



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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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