

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Hart Biologicals Ltd
2 Rivergreen Business Centre
Queens Meadow
Hartlepool
TS25 2DL
United Kingdom

Facility ID Number: F008334

Holds Certificate No:

MDSAP 829171

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design and development, manufacture, and distribution of in-vitro diagnostic reagents used in the management of haemostasis disorders, including nearpatient/point-of-care testing.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2026-02-20

Effective Date: 2026-02-20

Expiry Date: 2029-02-19



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