

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

Holds Certificate Number:

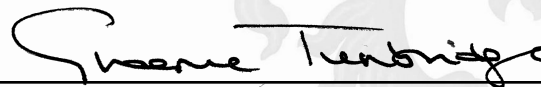
MD 764854

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

Design, development, manufacture, distribution, including subcontract manufacture, of in vitro diagnostic reagents, controls and diluents used in haemostasis testing.

Installation, servicing, and distribution of IVD instruments for haemostasis testing for clinical and near patient testing .

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2022-08-21

Latest Revision Date: 2026-03-30

Effective Date: 2026-03-30

Expiry Date: 2029-02-19



Page: 1 of 1

...making excellence a habit.™