

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:

Development, manufacture, sale and distribution, including sub-contract manufacture, of in vitro diagnostic reagents and the supply of own brand labelled equipment. Distribution and servicing of related test equipment.

Transfer from: AJA Europe
Certificate number: AJAEU/09/13196

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-08-21

Latest Revision Date: 2022-08-21

Effective Date: 2022-08-21

Expiry Date: 2024-01-10



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