



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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...making excellence a habit."

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 <u>online</u>. 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 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.