

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Biohope Scientific Solutions
for Human Health SL
C/ Santiago Grisolia 2, ed S2B
Tres Cantos 28760 - Madrid
Spain

Holds Certificate Number:

MD 711005

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

Design and manufacture of in vitro diagnostic immunoassays and related software for the determination of individualized patient response pattern to immunosuppressive medication.
Previous certificate expired 1 December 2022
Recertification audit ended 24 November 2022

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-12-02

Latest Revision Date: 2022-12-19

Effective Date: 2022-12-19

Expiry Date: 2025-12-01

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