

Certificate of Registration

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

This is to certify that:

HemoCue AB
Kuvettgatan 1
SE-262 71 Ängelholm
Sweden


Holds Certificate Number:

MD 667920

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 Development, Manufacture and Distribution of in-vitro diagnostic instruments and reagents for hematology and clinical chemistry parameters including point of care and professional use. Servicing of in-vitro diagnostic instruments for hematology and clinical chemistry.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2017-12-13

Latest Revision Date: 2025-01-13

Effective Date: 2025-02-07

Expiry Date: 2028-02-06

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