



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 IVD test systems for hematology and clinical chemistry parameters.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-12-13

Latest Revision Date: 2022-02-02

Effective Date: 2022-02-07 Expiry Date: 2025-02-06

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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 online. Printed copies can be validated at www.bsigroup.com/ClientDirectory