

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.

Gary E Slack

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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