

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

HemoCue AB
Kuvettgatan 1
Ängelholm
262 71
Sweden

Holds Certificate Number:

MD 667920

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 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:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-12-13

Latest Revision Date: 2017-12-13

Effective Date: 2017-12-13

Expiry Date: 2019-02-28



003

Page: 1 of 1

...making excellence a habit.™