

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

**HemoCue AB**  
Kuvettgatan 1  
SE-262 71 Ängelholm  
Sweden

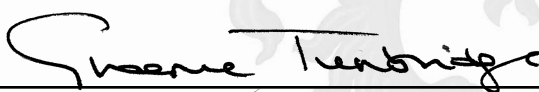
Holds Certificate Number:

FM 703986

and operates a Quality Management System which complies with the requirements of 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: 2016-07-01

Latest Revision Date: 2025-01-30

Effective Date: 2025-02-07

Expiry Date: 2028-02-06

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