



Product Service

# CERTIFICATE

No. Q1N 16 03 32060 016

**Holder of Certificate:** HemoCue AB



Kuvettgatan 1  
26271 Ängelholm  
SWEDEN

**Facility(ies):**

HemoCue AB  
Kuvettgatan 1, 26271 Ängelholm, SWEDEN



**Certification Mark:**



**Scope of Certificate:** Design and development, production and distribution of test-systems for In-Vitro Diagnostic

**Applied Standard(s):**

EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 713077639

**Valid from:** 2016-08-01  
**Valid until:** 2019-07-31

**Date,** 2016-06-14

*S. Preiß*  
Stefan Preiß



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