By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 727883 R000

Manufacturer: HemoCue AB

Address:
Kuvettgatan 1
SE-262 71 Ängelholm
Sweden

Single Registration Number: SE-MF-000000697

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-07-20** Date: **2021-07-20** Expiry Date: **2026-07-19**

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Device Schedule:

Intended Purpose as per the Instructions for Use:
The HemoCue® Hb 201 Systems are intended for quantitative determination of hemoglobin in capillary, venous or arterial whole blood using specially designed analyzers and specially designed microcuvettes, the HemoCue® Hb 201 Microcuvettes. HemoCue® Hb 201 Microcuvettes are for in vitro diagnostic use only. The HemoCue® Hb 201 Systems are automated systems for professional use, intended for near-patient (point-of-care) and laboratory testing. Indication for use is quantitative determination of hemoglobin to support clinical decisions in the detection of anemias, erythrocytosis and polycythemias.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
Hemocue Hb 201 Microcuvettes	1117	IVR 0605	Class B near-patient test	7311091117XXBW

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3182373	Issued.

First Issued: **2021-07-20** Date: **2021-07-20** Expiry Date: **2026-07-19**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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