



LISTA DISPOZITIVILOR MEDICALE (1)

Cod	Numărul de catalog	Denumirea	Modelul
DM000894215		Analizator	Hb 801

15 25 50 Tot

Pagina 1 de 1 (1 obiecte) < 1 >

← Înapoi



LISTA DISPOZITIVILOR MEDICALE (1)

Cod	Numărul de catalog	Denumirea	Modelul
DM000894217		Microcuvetă pentru determinarea hemoglobinei	Hb 801

15 25 50 Tot

Pagina 1 de 1 (1 obiecte) < 1 >

← Înapoi

EU Technical Documentation Assessment Certificate

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

IVDR 727885 R000

Manufacturer: HemoCue AB

Address:

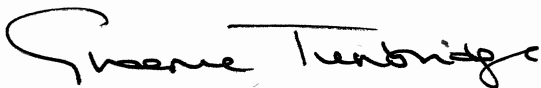
Kuvettgatan 1
SE-262 71 Ängelholm
Sweden

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):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-06-27**

Date: **2022-06-27**

Expiry Date: **2027-06-26**

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EU Technical Documentation Assessment Certificate

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

IVDR 727885 R000

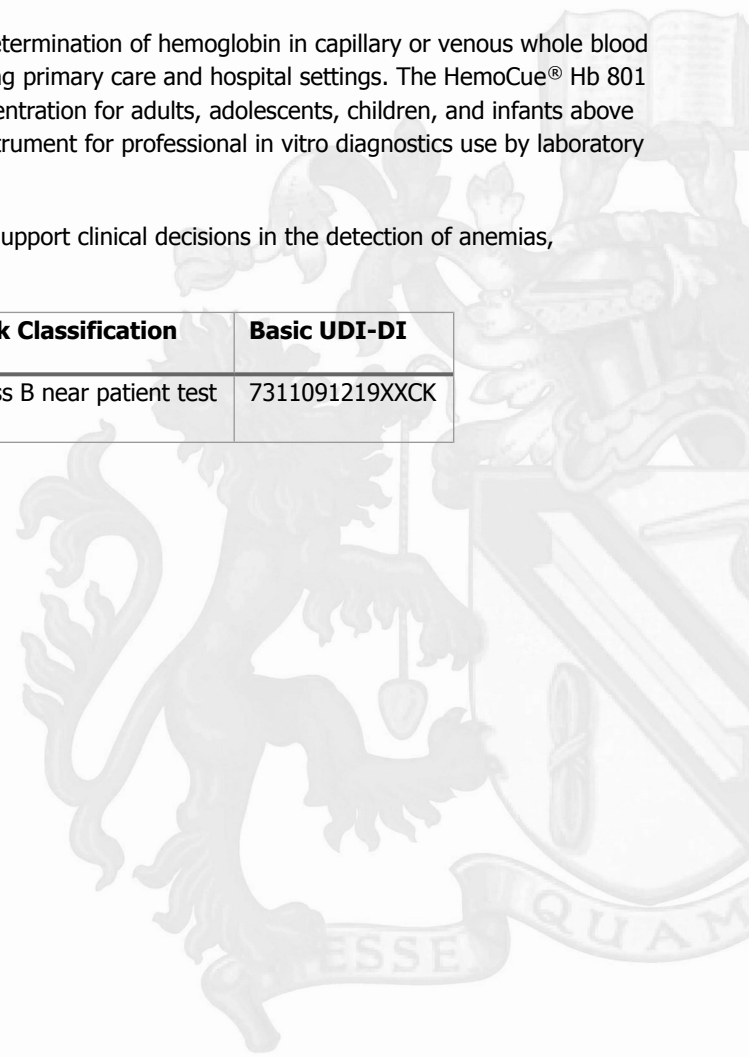
Device Schedule:

Intended purpose as per the Instructions for Use:

The HemoCue® Hb 801 Analyzer is intended for the quantitative determination of hemoglobin in capillary or venous whole blood in near-patient (point-of-care) and blood donation settings, including primary care and hospital settings. The HemoCue® Hb 801 Analyzer is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old. The HemoCue® Hb 801 Analyzer is an automated instrument for professional in vitro diagnostics use by laboratory personnel and healthcare professionals.

Indications 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 801 Analyzer	1219	IVR 0605	Class B near patient test	7311091219XXCK



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EU Technical Documentation Assessment Certificate

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IVDR 727885 R000

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	3182376	Issued



First Issued: **2022-06-27**

Date: **2022-06-27**

Expiry Date: **2027-06-26**

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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.

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

Page: 1 of 1



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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 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: 2017-12-13

Latest Revision Date: 2025-01-13

Effective Date: 2025-02-07

Expiry Date: 2028-02-06

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February 1, 2019

HemoCue AB
Maria Fagerberg
Director Regulatory Affairs
Kuvettgatan 1
Angelholm, Sweden SE-26271

Re: K181751

Trade/Device Name: HemoCue Hb 801 System
Regulation Number: 21 CFR 864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: Class II
Product Code: GKR
Dated: June 27, 2018
Received: July 2, 2018

Dear Maria Fagerberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Ängelholm, November 27, 2025

HEMOCUE AB

EU DECLARATION OF CONFORMITY

Manufacturer's name:	HemoCue AB Kuvettgatan 1 SE-262 71 Ängelholm Sweden
Single Registration Number (SRN):	SE-MF-000000697
Product Name/Trade Name:	HemoCue® Hb 801 Analyzer EMDN code: W02020699 RAPID TEST HEMATOLOGY / HISTOLOGY / CYTOLOGY INSTRUMENTS - OTHER
	Intended Purpose The HemoCue Hb 801 System is intended for the quantitative determination of hemoglobin in capillary or venous whole blood in near-patient (point-of-care) and blood donation settings, including primary care, hospital settings and road ambulance setting. The HemoCue Hb 801 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old. The HemoCue Hb 801 System is an automated system for professional in vitro diagnostic use by laboratory personnel and healthcare professionals.
	Indication for Use Indications for use is quantitative determination of hemoglobin to support clinical decisions in the detection of anemias, erythrocytosis and polycythemias.
Basic UDI-DI:	7311091219XXCK
Risk class:	The device is classified as Class B according to rule 4b and 6 of the Regulation (EU) 2017/746, Annex VIII.
Notified Body name and identification number:	BSI Group The Netherlands B.V. Notified Body Number 2797

Conformity Assessment route: Regulation (EU) 2017/746, Annex IX
Certificate number and expiry date: IVDR 727885. Expiry date: 2027-06-26
Common specifications: No applicable common specifications available

We, HemoCue AB, solely under our responsibility, herewith declare that the above-mentioned product is in conformity with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices, and Directive 2011/65/EU (RoHS).

All supporting documentation is retained under the premises of the manufacturer.

HemoCue AB



Brian Bratz-Boyd
Senior Director RA/QA
Ängelholm, Sweden

HEMOCUE AB**EU DECLARATION OF CONFORMITY**

Manufacturer's name: **HemoCue AB**
Kuvettgatan 1
SE-262 71 Ängelholm
Sweden

Single Registration Number (SRN): SE-MF-000000697

Product Name/Trade Name: HemoCue® Hb 801 Microcuvettes
EMDN codes: W0501010199 - VENOUS OR
ARTERIOUS BLOOD COLLECTION DEVICES – OTHER,
W0501010299 - CAPILLARY BLODD COLLECTION
DEVICES - OTHER

Intended Purpose

The HemoCue Hb 801 System is intended for the quantitative determination of hemoglobin in capillary or venous whole blood in near-patient (point-of-care) and blood donation settings, including primary care, hospital settings and road ambulance setting.

The HemoCue Hb 801 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old. The HemoCue Hb 801 System is an automated system for professional in vitro diagnostics use by laboratory personnel and healthcare professionals.

Indications for Use

Indications for use is quantitative determination of hemoglobin to support clinical decisions in the detection of anemias, erythrocytosis and polycythemias.

Basic UDI-DI: 7311091119XXC8

Risk class: The device is classified as Class A according to rule 4b and 5c of the Regulation (EU) 2017/746, Annex VIII.

Notified Body name and identification number: Not applicable (non-sterile device)



Conformity Assessment route: Regulation (EU) 2017/746, Article 48(10)
Certificate number and expiry date: Not applicable
Common specifications: No applicable common specifications available

We, HemoCue AB, solely under our responsibility, herewith declare that the above mentioned product is in conformity with the Regulation (EU) 2017/746.

All supporting documentation is retained under the premises of the manufacturer.

HEMOCUE AB

Rikard Almåker
Director RA