

UJIŠTĚNÍ O PROHLÁŠENÍ O SHODĚ

Dovozce: INMED-IN, s.r.o.
Antala Staška 32
142 00 Praha 4
IČO: 25689568

*zdravotnického prostředku: 121707 Hb201+ analyser g/l 0419012132
111708 Hb201 microcuvette 040021
výrobce HemoCue, Švédsko*

tímto ve smyslu § 13 odst. 5 Zákona č. 22/1997 Sb. o technických požadavcích na výrobky a o změně a doplnění některých zákonů

ujišťuje
Nemocnici Olomouc

o tom, že vydal Prohlášení o shodě zdravotnického prostředku s technickými předpisy a o dodržení stanoveného postupu posouzení shody. Prohlášení o shodě obsahuje veškeré náležitosti uvedené v nařízení vlády č. 181/2001 Sb. ve znění nařízení vlády č. 336/2001 Sb. a bylo vydáno dne 1. 1. 2000 (HemoCue) (Owen Mumford), 29.11. 2002 a 13.3. 2003 (B.H.K. Holding).

Originál Prohlášení o shodě je uložen u výše uvedeného dovozce.

V Praze dne 29. 6. 2004

INMED
Antala
142 00
Tel./Fax
.....
MUDr. Jana Kubcová
ředitelka společnosti

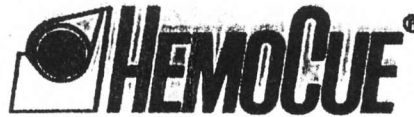
Společnost je zapsána v obchodním rejstříku, vedeném Městským soudem v Praze oddíl C, vložka 601401 dne 24. srpna 1998 pod číslem 62134/2000.

CERTIFICATE

No. Q1N 04 08 32060 007



Holder of Certificate:



HemoCue AB
Kuvettgatan 1
26223 Ängelholm
Sweden

Facility(ies):

HemoCue AB
Kuvettgatan 1, 26223 Ängelholm, Sweden

Certification Mark:



Scope of Certificate:

Design and development, production
and distribution of test systems for
In-vitro Diagnostic

Applied Standard(s):

ISO 13485:2003
Medical Devices -
Quality Management Systems -
Requirements for Regulatory Purposes

The Certification Body of TÜV PRODUCT SERVICE GMBH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standards. See also notes overleaf.

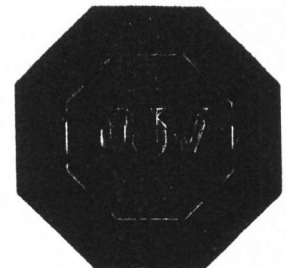
Report No.:

70074624

Valid until:

2007-07-31

Date, 2004-09-08



TÜV PRODUCT SERVICE GMBH
Zertifizierstelle
Ridlerstraße 65 D-80339 München
Gruppe TÜV Süddeutschland

Akkreditiert durch



Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten

vertreten im



ZLG-ZQ-999.98.12-46



COPY

DET NORSKE VERITAS

QUALITY SYSTEM CERTIFICATE

Certificate No. 2000-SKM-AQ-1331

This is to certify that

THE QUALITY SYSTEM
of

Flextronics Western Europe

at

KARLSKRONA, STOCKHOLM (SÄTRA, NACKA STRAND), GOTHENBURG,
KATRINEHOLM, VÄSTERÅS, VISBY, MALMÖ AND LINKÖPING
IN SWEDEN

has been found to conform with the Quality System Standard
SS-EN ISO 9001:1994

This Certificate is valid for the following product or service ranges:

DESIGN, MANUFACTURING, DISTRIBUTION, INSTALLATION
AND SERVICE OF ELECTRONIC PRODUCTS AND SYSTEMS

Place and date

Stockholm, 2001-10-01

for the Accredited Unit

DNV Certification AB, Sweden

This Certificate is valid until

2003-08-31

Company initially certified

by SIS SAQ Certifiering AB

Certificate No 570

1997-11-28





Tuomo Räsänen

Management Representative



Lack of fulfilment of condition as set out in the Appendix may render this certificate invalid



HEMOCUE AB

EC DECLARATION OF CONFORMITY

Manufacturer's name: HemoCue AB

Manufacturer's address: Box 1204
SE-262 23 Ängelholm
Sweden

Product name: HemoCue Hb 201⁺ analyzer
HemoCue Hb 201 Microcuvettes

Classification: General – not according to Annex II

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EEC for In Vitro Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Ängelholm January 24, 2005

A handwritten signature in black ink that reads "Anders Williamsson".

Anders Williamsson
Managing Director

Guaranteed Performance



from HemoCue



HemoCue's hemoglobin testing systems for the point of care achieve a precision and accuracy matching that of a central laboratory. We guarantee this by ensuring that all hemoglobin instruments and cuvettes leaving our production facility meet or exceed rigorous specifications for:

- 1. Within lot variation**
- 2. Lot-to-lot variation**
- 3. Calibration**
- 4. Instrument-to-instrument variation**
- 5. Total system variation**

Our factory-calibrated instruments require no adjustment or recalibration, and our cuvettes are produced without any clinically significant lot-to-lot variation. Handled appropriately, HemoCue hemoglobin systems provide consistent, lab-quality results at the point of care.

