



Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 14 05 73112 014

Manufacturer: **CERAGEM MEDISYS Inc.**
16, Jeongja 1-gil, Seonggeo-eup
Seobuk-gu
Cheonan-si, Chungcheongnam-do 331-833
REPUBLIC OF KOREA

EC-Representative: **Obelis s.a.**
Bd. General Wahis 53
1030 Brussels
BELGIUM

Product Category(ies): **Blood glucose measuring systems for self testing
,Lactate and/or Hemoglobin measuring system for
self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report No.: 74937909

Valid from: 2014-06-16
Valid until: 2019-06-15



Date, 2014-06-18

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Model(s):

Blood Glucose Monitoring System

- Blood Glucose Test Meter
- Blood Glucose Test Strip
- Glucose Control Solution
- Test Electrode

Model Name

MG 200

Brand Name

LABONACHECK GLUPPY /
CERA-CHEK GOLD

MG 210

LABONACHECK WING

MG 220

LABONACHECK WING2 /
CERA-CHEK WING

G 300

CERA-CHEK 1070

G 400

CERA-CHEK 1Code

Lactate Measuring System

- Lactate Test Meter
- Lactate Test Strip
- Lactate Control Solution
- Test Electrode

Model Name

L 400

Brand Name

CERA-CHEK Lactate

Hemoglobin Measuring System

- Hemoglobin Test Meter
- Hemoglobin Test Strip
- Hemoglobin Control Solution
- Test Electrode

Model Name

H 400

Brand Name

CERA-CHEK Hb Plus

Blood Glucose, Hemoglobin, Lactate Monitoring System

- Blood Glucose, Hemoglobin, Lactate Test Meter
- Blood Glucose Test Strip
- Hemoglobin Control Solution
- Test Electrode
- Blood Lactate Test Strip
- Lactate Control Solution
- Test Electrode

Model Name

M 400

Brand Name

CERA-CHEK 3 in 1 GHL

Facility(ies):

CERAGEM MEDISYS Inc.
16, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu, Cheonan-si,
Chungcheongnam-do 331-833, REPUBLIC OF KOREA