

DECLARATION OF CONFORMITY

Manufacturers: **CERAGEM Medisys Inc.**
16, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu,
Cheonan-si, Chungcheongnam-do, Korea

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

Product Name: M 400 Blood Glucose, Hemoglobin, Lactate Monitoring System

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

Blood Hemoglobin 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

Classification: Self testing device
Conformity Assessment: Directive Certificates for Systems
EC Certificate Annex IV.3 IVD

Route

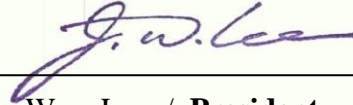
We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied: Refer to attachement 1.

Notified Body: TÜV SÜD Product Service GmbH (Identification no. 0123)
Ridlerstraße 65
80339 MÜNCHEN, Germany

EC Certificate: V1 13 09 73112 012

Start of CE-Marking: October 14, 2013
Place, Date of Issue: Republic of Korea / October 14, 2013
Signature:



Jin Woo Lee / **President**
On behalf of **CERAGEM Medisys Inc.**

Attachment 1, European Norms and Standards and other Documents supporting Technical Files (harmonized)

- ISO 18113-4:2013**, In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 4 : In vitro diagnostic reagents for self-testing(ISO 18113_4:2009)
- ISO 18113-5:2013**, In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 5 : In vitro diagnostic instruments for self-testing(ISO 18113_5:2009)
- EN 15223-1:2013**, Medical device- Symbols to be used with medical device labels, labeling and information to be supplied- Part 1: General requirements(ISO 15223-1:2012)
- EN 1658:2009**, Requirements for marking on in vitro diagnostic instruments
- EN ISO 13485:2012**, Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)
- EN ISO 13532:2002**, General requirements for in vitro diagnostic medical devices for self-testing
- EN 13612:2002**, Performance evaluation of in-vitro diagnostic medical devices
- EN 13640:2002**, Stability testing of in vitro diagnostic reagents
- EN ISO 14971:2012**, Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
- EN ISO 15197:2013**, In vitro diagnostic test systems - Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus
- ISO 15223-1:2012/Amd 1:2008**, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
- ISO 15223-2:2010**, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 2 : Symbol development, selection and validation
- ISO 17511:2003**, In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
- EN 60068-2-64:2008**, Environment testing - Part 2-64: Tests Fh: Vibration, broadband random and guidance
- EN 61000-4-2:2009**, Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test
- EN 61000-4-3:2006/A2:2010**, Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
- EN 61010-1:2010**, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- EN 61010-2-101:2002**, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (IEC 61010-2-101:2002, Modified)
- EN 61326-1:2013**, Electrical equipment for measurement, control, and laboratory use - EMC requirements - Part 1: General requirements
- EN 61326-2-6:2006**, Electrical equipment for measurement, control, and laboratory use - EMC requirements - Part 2-6: Particular requirements - in vitro diagnostic (IVD) medical equipment
- EN 60601-1-2:2007**, Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests