CERAGEM MEDISYS

CE 0123

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	**Brand Name**
M 400	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)
Ridlerstraβe 65
80339 MÜNCHEN, Germany

EC Certificate: V1 13 09 73112 012

CERAGEM MEDISYS

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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