GREEN CROSS MEDIS

CE 0123

DECLARATION OF CONFORMITY

Manufacturers: **GREEN CROSS MEDIS Corp.**
16, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu,
Cheonan-si, Chungcheongnam-do 31045, Korea

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

Product Name: Blood Glucose Monitoring System
Blood Glucose Test Meter
Blood Glucose Test Strip
Glucose Control Solution

Model Name	**Brand Name**
G 400	CERA-CHEK 1Code
	Check N
	GREEN-CHEK
	GREEN-DOCTOR
	GlucoCare
	Vital Plus

Classification: List B according to Annex II

Conformity Assessment: Directive Certificates for Systems
Annex IV without sections 4 and 6 of IVDD, 98/79/EC

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

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EC Certificate: V1 16 09 91763 006

Start of CE-Marking: October 13, 2016
Place, Date of Issue Republic of Korea / October 13, 2016

Applied product
(Manufacturing date) October 13, 2016

Signature: Young Pill Kim

Young Pill Kim / **Representative Director**
On behalf of **GREEN CROSS MEDIS Corp.**

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Attachment 1,

Product Name	**Blood Glucose Monitoring System** **Blood Glucose Test Meter** **Blood Glucose Test Strip** **Glucose Control Solution**
Model Name	**G 400**
GMDN Code	**Blood Glucose Monitoring System : 21 07 10 01** **Blood Glucose Test Meter : 21 01 10 01** **Blood Glucose Test Strip : 11 70 01 01** **Glucose Control Solution : 11 50 02 05**
Classification and Conformity Assessment Route	**List B according to Annex II of the Directive 98/79/EC Annex IV excluding sections 4 and 6 of IVDD(Directive 98/79/EC concerning IVD)**
Conformity Requirement	**EN ISO 13485:2012** **EN ISO 14971:2012** **EN ISO 15197:2015**
Notified Body	**TÜV SÜD Product Service GmbH (Identification no. 0123) Ridlerstraβe 65** **80339 MÜNCHEN, Germany**
EC Certificate	**V1 16 09 91763 006**

Attachment 2, European Norms and Standards and other Documents supporting Technical Files (harmonized)

EN ISO 18113-1;2011, In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-4;2011, In vitro diagnostic medical devices – Information supplied by the manufacturer
(labeling) – Part 4 : In vitro diagnostic reagents for self-testing
EN ISO 18113-5;2011, In vitro diagnostic medical devices – Information supplied by the manufacturer
(labeling) – Part 5 : In vitro diagnostic instruments for self-testing
EN 15223-1:2016, Medical device- Symbols to be used with medical device labels, labeling and information to be supplied- Part 1: General requirements
EN ISO 13485:2012, Medical devices - Quality management systems - Requirements for regulatory purposes
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 23640:2014, In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents
EN ISO 14971:2012, Medical devices - Application of risk management to medical devices (ISO 14971:2002)
EN ISO 15197:2003, In vitro diagnostic test systems - Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2003)
EN ISO 15197:2015 In vitro diagnostic test systems - Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2013)
ISO 15223-1:2012, 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
EN 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 (IEC 61010-1:2010)
IEC 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 61010-2-101:2015, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61326-1:2013, Electrical equipment for measurement, control, and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2013, 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
IEC 62304 Medical device software - Software life cycle processes
EN 62366:2008 , Medical devices-Application of usability engineering to medical devices