[별지 제41호 서식]
서울 서초구 동작대로 36
(방배동, 대광빌딩 3층)

공증인가 **대한법무법인**

TEL : (02) 590-0900(代)
FAX : (02) 3477-0957

Registered No. 2017 - 9037

Hợp chuẩn CS 4000.
+ Test + control.

NOTARIAL CERTIFICATE

Daehan Law Firm & Notary Office Inc.
DaeGwang B/D 3F, 36 Dongjak-daero,
Seocho-gu, Seoul, Korea
TEL : (02) 590-0900(代)
FAX : (02) 3477-0957

DAEHAN LAW FIRM & NOTARY OFFICE INC.

CS4000 DOC

210mm×297mm
보존용지(1종) 인쇄용지(특급) 70g/㎡

GREEN CROSS MEDIS

CE

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: Analyzer

CRP Test Kit
CRP Control Solution

HbA1c Test Kit
HbA1c Control Solution

Model Name	**Brand Name**
CS 4000	CERA-STAT 4000
	CERA-STAT

Classification: Others
Conformity Assessment: Annex III, without sections 6 of IVDD 98/79/EC
Full quality assurance system

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
Ridlerstraβe 65
80339 MÜNCHEN, Germany

QM Certificates
QM System ISO 13485: Q1N 16 08 91763 005

Start of CE-Marking: October 14, 2016

Vanthang

GREEN CROSS MEDIS

CE

Place, Date of Issue: Republic of Korea / October 14, 2016

Signature: Young Pill Kim

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

Attachment 1, 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 manufactucturer(labeling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011, In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2:In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011, In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)
EN ISO 13485:2012, Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2012)
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 14971:2012)
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)
ISO 15223-1:2010, 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 60601-1-4:1996/A1:1999, Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems (IEC 60601-1-4:1996/A1:1999)
EN 61000-4-2:1995/A2:2001, Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test
EN 61000-4-3:2006/A1:2008, Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
EN 61010-1:2001, 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 61326-1:2006, 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 60601-1-2:2001, Medical electrical equipment – Part 1-2: General requirements for safety– Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 62304 Medical device software - Software life cycle processes

[별지 제43호서식] 공증인가 **대한법무법인**

등부 **2017** 년 제 9037 호 Registered No. **2017** - 9037

인 증

위 선언문 ----------에 기재된 주식회사 녹십자메디스 대표이사 김영필의 대리인 이진만----------은(는) 본 공증인의 면전에서 위 본인이 기명날인한 것임을 자인하였다.

2017 년 06 월 15 일
이 사무소에서 위 인증한다.

공증인가 대한법무법인
소속 서울중앙지방검찰청
서울 서초구 동작대로 36
대광빌딩 3층

공증인 공증담당변호사

Notarial Certificate

LEE JIN MAN attorney-in-fact of
GREEN CROSS MEDIS Corporation.
Young Pill Kim / Representative Director

appeared before me and admitted said principal's subscription to the attached

DECLARATION OF CONFORMITY.
This is hereby attested on this
15 day of Jun. 2017 at this office.

Daehan Law Firm & Notary Office Inc.
Belong to Seoul Central District Prosecutors' Office
DaeGwang B/D 3F, 36 Dongjak-daero, Seocho-gu, Seoul, Korea

Attorney-at-law

HAHN BONG KYOO
This office has been authorized by the Minister of Justice, the Republic of Korea, to act as Notary Public since January 6, 2010 under Law No. 11823

ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI HÀN QUỐC
THE EMBASSY OF THE SOCIALIST REPUBLIC OF VIETNAM IN THE REPUBLIC OF KOREA

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia / *Country*: **Việt Nam** / *Vietnam*
Giấy tờ, tài liệu này / *This public document*
2. do Ông (Bà) / *has been signed by*: **Kim Byung Ho** ký
3. với chức danh / *acting in the capacity of*: Viên chức lãnh sự
4. và con dấu của / *bears the seal/stamp of*: **Bộ Ngoại giao Hàn Quốc** / *Ministry of Foreign Affairs of the Republic of Korea*

được chứng nhận / hợp pháp hóa lãnh sự / *Certified*
5. tại / *at*: **Hàn Quốc** / *The Republic of Korea* 6. ngày / *the*: **16/06/2017**
7. Cơ quan cấp / *by*: **Đại sứ quán nước CHXHCN Việt Nam tại Hàn Quốc** / *The embassy of the S.R. of Vietnam in the Republic of Korea*
8. Số / *No*: **6955 / CNLS/HPHLS**

Ký tên và đóng dấu / *Signature and seal/stamp*

Bí thư thứ nhất/First Secterary

Nguyễn Tấn Trung

ĐẠI SỨ QUÁN CHXHCN VIỆT NAM TẠI HÀN QUỐC

Ministry of Foreign Affairs
Republic of Korea

Seen at the Ministry of Foreign Affairs of the Republic of Korea. Valid only if submitted to foreign missions in the Republic of Korea.

1. Seoul, Korea 2. 15/06/2017
3. No. XXC2017U34M6NM
4. Signature **Kim Byoung Ho**

MINISTRY OF FOREIGN AFFAIRS OF THE REPUBLIC OF KOREA