



Certificate

No. Q5 091763 0014 Rev. 01

Holder of Certificate: **GC MEDIS Corp.**
16, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu
Cheonan-si, Chungcheongnam-do 31045
REPUBLIC OF KOREA

Certification Mark:



Scope of Certificate: **Design, Development, Production and Distribution of Blood Glucose Monitoring System, HbA1c Test System, Hemoglobin Measuring System, CRP Test System using Immunochromatography Assay, and Lactate Measuring System**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 091763 0014 Rev. 01

Report No.: 74963312, 74963312_CN

Valid from: 2022-10-14
Valid until: 2025-10-13

Date, 2022-10-11



Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 091763 0014 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

GC MEDIS Corp.
16, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu, Cheonan-si,
Chungcheongnam-do 31045, REPUBLIC OF KOREA

Design, Development, Production and Distribution of Blood
Glucose Monitoring System, HbA1c Test System, Hemoglobin
Measuring System, CRP Test System using
Immunochromatography Assay, and Lactate Measuring System

GC MEDIS Corp.
503, 5F, 95, 2gongdan 2-ro, Seobuk-gu, Cheonan-si,
Chungcheongnam-do 31075, REPUBLIC OF KOREA

Production of HbA1c Test System

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Certificate

No. Q5 091763 0014 Rev. 00

Holder of Certificate: **GREEN CROSS MEDIS Corp.**
16, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu
Cheonan-si, Chungcheongnam-do 31045
REPUBLIC OF KOREA

Facility(ies): GREEN CROSS MEDIS Corp.
16, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu, Cheonan-si,
Chungcheongnam-do 31045, REPUBLIC OF KOREA

GREEN CROSS MEDIS Corp.
503, 5F, 95, 2gongdan 2-ro, Seobuk-gu, Cheonan-si,
Chungcheongnam-do 31075, REPUBLIC OF KOREA

Certification Mark:



Scope of Certificate: **Design, Development, Production and Distribution of Blood Glucose Monitoring System, HbA1c Test System, Hemoglobin Measuring System, CRP Test System and Lactate Measuring System**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74954490

Valid from: 2019-10-14

Valid until: 2022-10-13

Date, 2019-09-11

Stefan Preiß
Head of Certification/Notified Body

ZERTIFIKAT • CERTIFICATE • 認 證 證 書 • CERTIFICADO • CERTIFICAT



Product Service

CERTIFICATE

No. Q1N 16 08 91763 005

Holder of Certificate: **GREEN CROSS MEDIS Corp.**
 16, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu
 Cheonan-si, Chungcheongnam-do 31045
 REPUBLIC OF KOREA

Facility(ies): GREEN CROSS MEDIS Corp.
 16, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu,
 Cheonan-si, Chungcheongnam-do 31045,
 REPUBLIC OF KOREA



Certification Mark:



Scope of Certificate: **Design, Development, Production and Distribution of Blood Glucose Monitoring System, HbA1c Test System, Hemoglobin Measuring System, CRP Test System, Lactate Measuring System and Phototherapy System**

Applied Standard(s): EN ISO 13485:2012 + AC:2012
 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)
 DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74945989

Valid from: 2016-10-14
Valid until: 2019-10-13



Date, 2016-10-13

S. Preiß
 Stefan Preiß

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