Declaration of Conformity

Manufacturer:	GC MEDICAL SCIENCE CORP 26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun, Chungcheongbuk-do, 27632, REPUBLIC OF KOREA
EUROPEAN REPRESENTATIVE:	MT Promedt Consulting GmbH Altenhofstrase 80, D-66386 St. Ingbert, Germany
PRODUCT(MODEL NAME):	GREENCARE A1c Hemoglobin A1c Test Kit
CLASSIFICATION:	Others
EDMA Code:	11 70 01 07 00 : Reagent for HbA1c testing for professional
CONFORMITY ASSESSMENT ROUTE:	ANNEX Ⅲ of IVDD

WE HERE WITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:	See Attachment
(EC) CERTIFICATE(S):	EN ISO 13485:2016 , Q5 049753 0020(Rev. 01)
START OF CE-MARKING:	2018.07.01. (YYYY.MM.DD)

PLACE, DATE OF ISSUE:	Republic of Korea, 2022.05.24. (YYYY.MM.DD)
SIGNATURE:	
CE	**Serka, Kim** **QMR, Quality Management Division**

Attachment 1.

REFERENCES

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 18113-2:2011, 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 13485:2016, Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

EN 13612:2002, Performance evaluation of in vitro diagnostic medical devices

ISO 23640:2015, In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnos tic reagents

EN ISO 14971:2012, Medical devices - Application of risk management to medical devices (ISO 14971:2012)

EN ISO 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 17511:2003, In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials

EN 61010-1:2010/A1:2019, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

EN 61010-2-101:2017, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

EN 55011:2016 + A1: 2017 (Group 1, Class B), Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement

EN 61326–1:2021, Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements

IEC 61326-2-6:2021, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

EN 61000-3-2:2019, Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)

EN 61000-3-3:2013+A1:2019, Electromagnetic compatibility (EMC). Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with

rated current ≤ 16 A per phase and not subject to conditional connection

EN 62304:2006, Medical device software - Software life cycle processes

IEC 62366-1:2015, Medical devices -- Part 1: Application of usability engineering to medical devices

IEC 62304:2006, Medical device software -- Software life cycle processes

Attachment 2. The list of the Non-significant changes after May 26th 2022.
Change 1.

Manufacturer: GC Medical Science Corporation
26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun, Chungcheongbuk-do, 27632, REPUBLIC OF KOREA

EUROPEAN REPRESENTATIVE: MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7 66386 St. Ingbert Germany

PRODUCT(MODEL NAME): GREENCARE A1c Hemoglobin A1c Test Kit

The changes are as follows ;

Change of	Old	New
EU representative address	Altenhofstrase 80, D-66386 St. Ingbert, Germany	Ernst-Heckel-Straße 7 66386 St. Ingbert Germany
ISO certificate number	EN ISO 13485:2016, Q5 049753 0020(Rev. 01)	EN ISO 13485:2016, Q5 049753 0020(Rev. 02)

In accordance with the MDCG 2022-6 guidance, we warrant that these changes are a non-significant change.

This attachment belongs to the DoC, which has been issued on 2022.05.24.

Place, Date of Issue: Republic of Korea, 2023.03.31.

Signature:

Serka Kim

Serka, Kim
QMR, Quality Management Division

Change 2.

Manufacturer: GC Medical Science Corporation
26, Mugeuk-ro 65beon-gil, Geumwang-eup,
Eumseong-gun, Chungcheongbuk-do, 27632,
REPUBLIC OF KOREA

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

EUROPEAN REPRESENTATIVE: MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7 66386 St. Ingbert Germany

PRODUCT(MODEL NAME): GREENCARE A1c Hemoglobin A1c Test Kit

The changes are as follows ;

Change of	Old	New
Add the manufacturer information	MANUFACTURER GC Medical Science Corporation 26, Mugeuk-ro 65beon-gil, Geumwang-eup, Emseong-gun, Chungcheongbuk-do, 27632, REPUBLIC OF KOREA	MANUFACTURER Legal Manufacturer: GC Medical Science Corporation 26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun, Chungcheongbuk-do, 27632, REPUBLIC OF KOREA ● Manufacturing Site GC MEDIS Corp. 16, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 31045, REPUBLIC OF KOREA
Applied Standard Update (related Safety and EMC)	**EN 61010-1:2010**, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements **EN 61010-2-101:2015,** Safety requirements for electrical equipment for measurement, control and laboratory use	**EN 61010-1:2010/A1:2019**, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements **EN 61010-2-101:2017,** Safety requirements for electrical equipment for measurement, control and laboratory use

Change of	Old	New
	- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment **EN 55011:2009 + A1: 2010,** Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement **EN 61326–1:2013,** Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements **IEC 61326-2-6:2012,** Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment **EN 61000-3-2:2014,** Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) **EN 61000-3-3:2013,** Electromagnetic compatibility (EMC). Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection.	- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment **EN 55011:2016 + A1: 2017 (Group 1, Class B),** Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement **EN 61326–1:2021,** Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements **IEC 61326-2-6:2021,** Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment **EN 61000-3-2:2019,** Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) **EN 61000-3-3:2013+A1:2019,** Electromagnetic compatibility (EMC). Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection

In accordance with the MDCG 2022-6 guidance, we warrant that these changes are a non-significant change.

This attachment belongs to the DoC, which has been issued on 2022.05.24.

Place, Date of Issue: Republic of Korea, 2023.07.27.

Signature: Serka Kim

Serka, Kim

QMR, Quality Management Division

Change 3. Addition of Model name

We, GC Medical Science Corp., declares that GREENCARE A1c Hemoglobin A1c Test Kit and respons®A1c Hemoglobin A1c Test Kit are completely identical except model name.

Manufacturer:	GC Medical Science Corporation 26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun, Chungcheongbuk-do, 27632, REPUBLIC OF KOREA
EUROPEAN REPRESENTATIVE:	MT Promedt Consulting GmbH Ernst-Heckel-Straße 7 66386 St. Ingbert Germany
PRODUCT(MODEL NAME):	GREENCARE A1c Hemoglobin A1c Test Kit respons®A1c Hemoglobin A1c Test Kit

In accordance with the MDCG 2022-6 guidance, we warrant that these changes are a non-significant change.

This attachment belongs to the DoC, which has been issued on 2022.05.24.
Place, Date of Issue: Republic of Korea, 2023.10.05.

Signature:

Serka, Kim
QMR, Quality Management Division