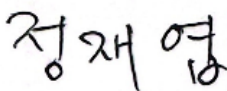


## Declaration of Conformity

<b>Manufacturer</b>	GC Medical Science Corporation [SRN No. KR-MF-000015840] 26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun, Chungcheongbuk-do 27632, REPUBLIC OF KOREA
<b>EC Representative</b>	MT Promedt Consulting GmbH [SRN No. DE-AR-000000085] Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany
<b>Product Name</b> <b>(Reference Number)</b>	GREENCARE A1c Analyzer (RT100M10) QDx A1c Advance (RT100M10) PocketChem A1c Advanced (107032) respons® A1c Analyzer (963100)
<b>Model Name</b>	RT-100
<b>Basic UDI-DI</b>	88061346A1CAKV
<b>Classification</b>	Class A based on Rule 5 of Annex VIII IVDR 2017/746

WE HERE WITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL REGULATION (EU) 2017/746 FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER.

<b>Standards Applied</b>	List of (Harmonized) standards for which documented evidence for compliance can be provided
<b>Conformity Assessment Route</b>	Article 48. 10., and Annex II, III of IVDR 2017/746
<b>Start of CE-marking</b>	2024.08.05
<b>Place, Date of Issue</b>	Chungcheongbuk-do, Republic of Korea, 2024.11.05

<b>Signature</b>		Jaeyeob Jung (PRRC)
		Signed for and on behalf of GC Medical Science Corporation

## Harmonised Standard list

<b>EN ISO 13485:2016</b>	Medical devices - Quality management systems - Requirements for regulatory purposes
<b>EN ISO 14971:2019/A11:2021</b>	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
<b>EN ISO 15223-1:2021</b>	Medical device- Symbols to be used with medical device labels, labeling and information to be supplied- Part 1: General requirements
<b>EN ISO 18113-1:2022</b>	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements
<b>EN ISO 18113-2:2022</b>	In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
<b>EN ISO 18113-3:2022</b>	In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)
<b>EN 13612:2002</b>	Performance evaluation of in vitro diagnostic medical devices
<b>EN ISO 15193:2009</b>	In vitro diagnostic medical devices —Measurement of quantities in samples of biological origin —Requirements for content and presentation of reference measurement procedures
<b>EN ISO 15194:2009</b>	In vitro diagnostic medical devices —Measurement of quantities in samples of biological origin —Requirements for certified reference materials and the content of supporting documentation
<b>ISO 20916:2019</b>	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice
<b>EN ISO 17511:2021</b>	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
<b>EN ISO 23640:2015</b>	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
<b>EN 61010-1:2010/A:2019</b>	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
<b>EN 61010-2-101:2017</b>	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
<b>EN IEC 61326-1:2021</b>	Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements
<b>EN IEC 61326-2-6: 2021</b>	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment



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<b>EN 55011:2016+ A1:2017+A11:2020 (Group1,ClassA)</b>	Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement
<b>EN 62304[2006]+AM1[2015]</b>	Medical device software - Software life cycle processes
<b>EN 62366-1:2015</b>	Medical devices - Part 1: Application of usability engineering to medical devices
<b>ISO/TR 20416:2020</b>	Medical devices — Post-market surveillance for manufacturers
<b>MEDDEV 2.12-1 Rev 8</b>	Guidance document - Market surveillance - Guidelines on a Medical Devices Vigilance System
<b>ISO 11014:2009</b>	Safety data sheet for chemical products – Content and order of sections
<b>European Regulation (EC) No 1272/2008</b>	European parliament and of the council of 16 December 2008 on classification, labeling and packaging of substances and mixtures
<b>DIRECTIVE 2012/19/EU WEEE(Waste Electrical and Electronic Equipment)</b>	

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