GC Medis

CE

# DECLARATION OF CONFORMITY

**Manufacturers**:

**GC MEDIS Corp.**
16, Jeongja 1-gil, Seonggeo-eup, Seobuk-gu,
Cheonan-si, Chungcheongnam-do 31045, Republic of Korea

**GC MEDIS Corp.**
503, 5F, 95, 2gongdan 2-ro, Seobuk-gu, Cheonan-si,
Chungcheongnam-do 31075, Republic of Korea

**EC Representative**:

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

**Product Name**:

HbA1c Analyzer
HbA1c Test Kit
Control Solution

| **Model Name** | **Brand Name** |
|---|---|
| MH 200 | LabonaCheck™ A1c |

**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. GC MEDIS corp. is exclusively responsible for the declaration of conformity.*

**Standards applied**: Refer to attachement 1.

**Notified Body**:

TÜV SÜD Product Service GmbH
Ridlerstraβe 65
80339 MÜNCHEN, Germany

**QM Certificates**

**QM System ISO 13485**: Q5 091763 0014 Rev. 01

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**Start of CE-Marking**: January 26, 2011

**Place, Date of Issue**: Republic of Korea / October 11, 2022

**Applied product (Manufacturing date)** October 11, 2022

**Signature**:

Young Hee, Sagong / **Representative Director**
On behalf of **GC MEDIS 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 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 17511:2021**, In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
**EN ISO 13485:2016/A11:2021, Medical devices -** Quality management systems - Requirements for regulatory purposes (ISO 13485:2012)
**EN 13612:2002,** Performance evaluation of in vitro diagnostic medical devices
**EN ISO 23640:2015,** In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
**EN ISO 14971:2019/A11:2021,** Medical devices - Application of risk management to medical devices (ISO 14971:2019)
**EN ISO 15223-1:2021**, Medical device- Symbols to be used with medical device labels, labeling and information to be supplied- Part 1: General requirements
**EN 55011:2009+A1:2010 CISPR11:2010)(Group1, Class B),** Industrial, scientific and medical equipment– Radio-frequency disturbance characteristics Lim-its and methods of measurement
**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 61000-3-2:2013,** Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)(IEC 61000-3-2:2013)
**EN 61000-3-3:2013,** Elec-tro-mag-netic com-pat-i-bil-ity (EMC) — Part 3 – 3: Lim-its –Lim-i-ta-tion of volt-age changes, volt-age fluc-tu-a-tions and flicker in pub-lic low-voltage sup-ply sys-tems, for equip-ment with rated cur-rent ≤ 16 A per phase and not sub-ject to con-di-tional con-nec-tion (IEC 61000–3–3:2013)
**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 - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
**EN 62304:2008** Medical device software - Software life cycle processes