OHC
OSANG HEALTHCARE

Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 0300 Fax: 82 031 460 0401
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# EU Declaration of Conformity

| | |
|---|---|
| Device Trade Name: | HemoCue HbA1c 501 Analyzer |
| Device Model Name: | IGM-0026BM |
| Device Basic UDI-DI | 880911590IGM0026BMUN |
| Device Reference No.: | Included in "Attachment #2" |
| Device Classification: | Class A Rule5(b) in ANNEX VIII |
| Conformity Assessment Route: | Annex II and III Technical Documentation<br>Annex IV Self Declaration of Conformity<br>Annex V CE Marking |
| Intended Purpose | The HemoCue HbA1c 501 Analyzer is a near-patient testing (NPT) in vitro diagnostic (IVD) automated medical device intended for quantitative measurement of hemoglobin A1c (HbA1c). This device is intended for healthcare professionals at hospitals, clinics, and clinical/medical laboratories and must only be used with HemoCue HbA1c 501 Test Cartridge. |
| Quality Control of Device | 1) Trade Name : HemoCue HbA1c 501 Daily Check Cartridge<br>Model Name : IGM-0026BMD<br>Basic UDI-DI : 880911590IGM0026BMDAZ<br>2) Trade Name : HemoCue HbA1c 501 Monthly Check Cartridge<br>Model Name : IGM-0026BMM<br>Basic UDI-DI : 880911590IGM0026BMMBK |
| Intended purpose of Quality Control | The HemoCue HbA1c 501 Daily & Monthly Check Cartridge is intended for performing quality control to evaluate the optical performance of the analyzer and calibrate the analyzer to maintain the specified performance. This cartridge does not require any additional sample collection. The HemoCue HbA1c 501 Daily & Monthly Check Cartridge must only be used with the HemoCue HbA1c 501 Analyzer |
| Manufacturer: | **OSANG Healthcare Co., Ltd.** |
| Address | 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, |
| Country : | Republic of Korea |
| Tel : | +82-31-460-0300 |
| Fax : | +82-31-460-0401 |
| SRN : | KR-MF-000032605 |
| Authorized Representative | **Obelis S.A.** |
| Address : | Bd. Général Wahis 53, 1030 Brussels Belgium |
| Tel : | +32 2 732 5954 |
| Fax : | +32 2 732 6003 |
| SRN : | BE-AR-000000106 |
| Attachments: | 1-1. List of applied standards<br>1-2. List of applied Regulations/Acts<br>2. Product Codes and Refernece List |

We hereby declare that this EU declaration of conformity is issued under the sole responsibility of the manufacturer and the above mentioned product/s is in conformity with the REGULATION 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL for *in vitro* diagnostic medical devices. We also declare that the device complies fully with all applicable sections of General Safety and Performance Requirements Checklist and standards/regulations/acts in "Attachment #1".
As well as the DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 8 JUNE 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Place: Anyang-si, Republic of Korea
Date: 06 / Sep / 2024

조 현규

Hyun-Kyu Cho / PRRC of OSANG Healthcare Co., Ltd.

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# Attachment #1-1. List of applied Standards

| No. | Title of standards | Contents |
|---|---|---|
| 1 | EN ISO 13485:2016 | Medical devices − Quality management systems − Requirements for regulatory purposes |
| 2 | EN ISO 14971:2019 | Medical devices − Application of risk management to medical devices |
| 3 | ISO/TR 24971:2020 | Medical devices — Guidance on the application of ISO 14971 |
| 4 | IEC 80001-1:2021 | Application of risk management for IT-networks incorporating medical devices<br>− Part 1: Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software |
| 5 | IEC TR 80001-2-1:2012 | Application of risk management for IT-networks incorporating medical devices<br>− Part 2-1: Step-by-step risk management of medical IT-networks − Practical applications and examples |
| 6 | IEC TR 80001-2-2:2012 | Application of risk management for IT-networks incorporating medical devices<br>− Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls |
| 7 | UL 2900-2-1:2023 | Software Cybersecurity for Network-Connectable Products,<br>Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems |
| 8 | ISO 15223-1:2021 | Medical devices — Symbols to be used with information to be supplied by the manufacturer<br>- Part 1: General requirements |
| 9 | ISO 18113-1:2022 | In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)<br>- Part 1: Terms, definitions, and general requirements |
| 10 | ISO 18113-2:2022 | In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)<br>- Part 2: In vitro diagnostic reagents for professional use |
| 11 | ISO 18113-3:2022 | In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)<br>- Part 3: In vitro diagnostic instruments for professional use |
| 12 | ISO 7000:2004 | Graphical symbols for use on equipment − Index and synopsis |
| 13 | IEC 60601-1-2_2014_AMD1_2020CSV | Medical electrical equipment − Part 1-2: General requirements for basic safety and essential performance<br>− Collateral Standard: Electromagnetic disturbances − Requirements and tests |
| 14 | IEC 61010-1:2012/AMD1:2016/COR1:2019 | Safety requirements for electrical equipment for measurement, control, and laboratory use<br>- Part 1: General requirements |
| 15 | IEC 61010-2-101:2018 RLV | Safety requirements for electrical equipment for measurement, control and laboratory use − Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment |
| 16 | IEC 61326-1:2020 | Electrical equipment for measurement, control and laboratory use − EMC requirements<br>− Part 1: General requirements |
| 17 | IEC 61326-2-6:2020 | Electrical equipment for measurement, control and laboratory use - EMC requirements<br>- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment |
| 18 | IEC 62366-1:2015+AMD1_2020 CSV | Medical devices − Part 1: Application of usability engineering to medical devices |

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| No. | Title of standards | Contents |
|---|---|---|
| 19 | IEC TR 62366-2:2016 | Medical devices − Part 2: Guidance on the application of usability engineering to medical devices |
| 20 | ANSI / AAMI HE75:2009 / (R) 2018 | Human factors engineering Design of medical devices |
| 21 | EN 62304:2006 /A1:2015 | Medical device software − Software life-cycle processes |
| 22 | IEC 62443-4-2_2019 | Security for industrial automation and control systems − Part 4-2: Technical security requirements for IACS components |
| 23 | ASTM D4169-22 | Standard Practice for Performance Testing of Shipping Containers and Systems |
| 24 | ISO 17511:2020 | In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples |
| 25 | ISO/TR 20416:2020 | Medical devices — Post-market surveillance for manufacturers |

## Attachment #1-2. List of applied Regulations/Acts

| No. | Title of Regulations/Acts | Contents |
|---|---|---|
| 1 | IVDR 2017/746 | In Vitro Diagnostic Regulations |
| 2 | Directive 2012/19/EU | Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) |
| 3 | Regulation (EC) No 1272/2008 | REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 |
| 4 | Regulation (EC) No 1907/2006 | REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Direc-tive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC |
| 5 | 80_181_EEC | COUNCIL DIRECTIVE of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC |
| 6 | MFDS, No. 16433 | Act on In Vitro Diagnostic Medical Devices |
| 7 | MDCG 2019-16 rev.1 | Guidance on Cybersecurity for medical devices |
| 8 | FDA-2013-D-0616 | Content of Premarket Submissions for Management of Cybersecurity in Medical Devices |
| 9 | MDCG 2022-2 | Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs) |

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# Attachment #2. Catalogue No. (=REF)

| Catalogue No. (=REF) | Ordering Information | |
|---|---|---|
| 405210 | HemoCue HbA1c 501 Analyzer Full Set (Box) |  |
| **#** | **Device Name** | **Quantity** |
| 1 | HemoCue HbA1c 501 Analyzer | 1 |
| 2 | Power adapter & AC/DC Cable | 1 |
| 3 | HemoCue HbA1c 501 Daily Check Cartridge | 1 |
| 4 | HemoCue HbA1c 501 Monthly Check Cartridge | 1 |
| 5 | Operation manual | 2 |
| 6 | Quick Reference Guidance | 1 |
| 7 | Fan filter | 5 |

| Catalogue No. (=REF) | Ordering Information | |
|---|---|---|
| 405112 | HemoCue HbA1c 501 Daily Check Cartridge (Pouch) |  |
| **#** | **Device Name** | **Quantity** |
| 1 | HemoCue HbA1c 501 Daily Check Cartridge | 1 |

| Catalogue No. (=REF) | Ordering Information | |
|---|---|---|
| 405111 | HemoCue HbA1c 501 Monthly Check Cartridge Set 1 (Box/6Test) |  |
| **#** | **Device Name** | **Quantity** |
| 1 | HemoCue HbA1c 501 Monthly Check Cartridge | 6 |