

## EU Declaration of Conformity

Common Name:

**Blood Glucose Monitoring System for Self-Testing**

Trade Name:

**EasyGluco**

Model Name:

**IGM-0002A**

Basic UDI

**Included in "Attachment #2"**

Product Reference No.:

**Included in "Attachment #2"**

Classification:

**List B**

According to ANNEX II of IVDD 98/79/EC

Blood Glucose Measuring systems for Self-testing including related control materials

**Annex IV Without section 4 and 6 of the IVDD**

**98/79//EC**

Conformity assessment based on a quality management system and on assessment of technical documentation

Conformity Assessment Route:

V1 001395 0018 Rev.04

Number of EC Certificate:

May 18th, 2022

Date of Issue:

May 26th, 2025

Expire date of the Certificate:

May 18th, 2022

Valid From:

**OSANG Healthcare Co., Ltd.**

Manufacturer:

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SRN

**TÜV SÜD PRODUCT SERVICE GmbH**

Notified Body:

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1. List of applied standards
2. Basic UDI and Product Code

EU Representative:

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 DIRECTIVE 98/79/EC 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 Essential Requirements Checklist and standards in "Attachment #1".

Place: Anyang-si, Korea



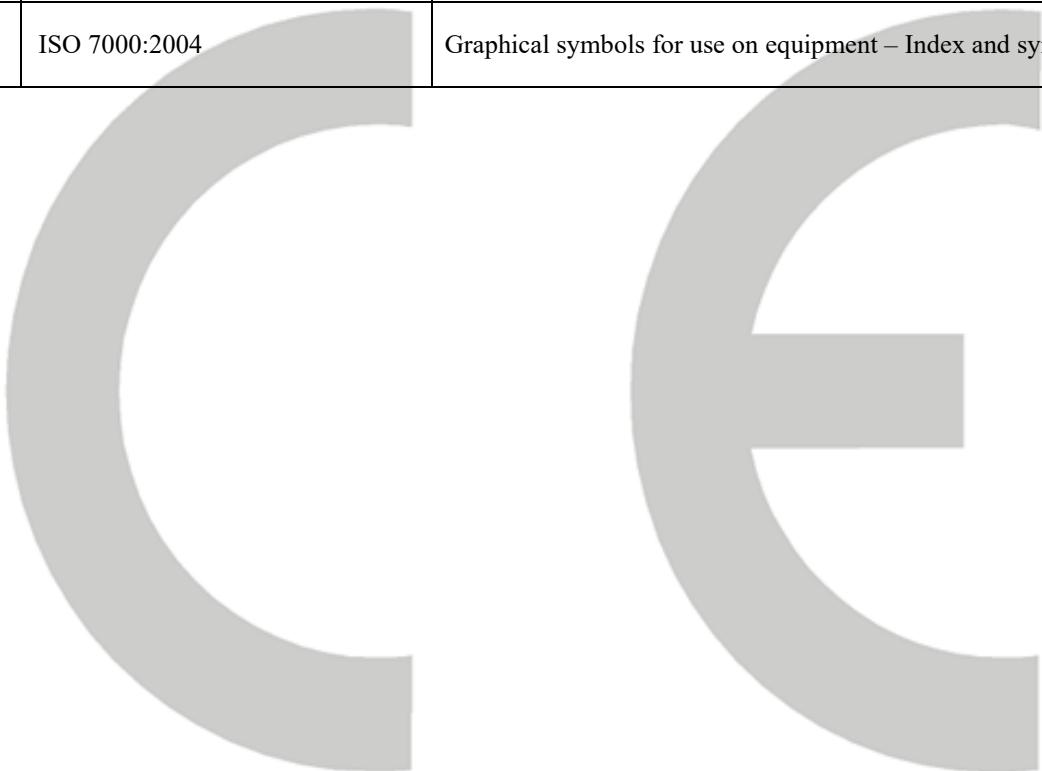
Date:

Seung Eok, Hong / CEO  
OSANG Healthcare Co., Ltd.

## **Attachment #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 15197:2015	In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
3	EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
4	EN ISO 17511:2003	Measurement of quantities in biological samples-Metrological traceability of values assigned to calibrators and control materials
5	EN ISO18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
6	EN ISO18113-4:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing
7	EN ISO18113-5:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing
8	EN 13532:2002	General requirements for in vitro diagnostic medical devices for self-testing
9	EN 13612:2002	Performance evaluation of in vitro diagnostic reagents
10	EN ISO 23640:2015	In vitro diagnostic medical devices – evaluation of stability of in vitro diagnostic reagents
11	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
12	EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control and laboratory use; General Requirements
13	IEC 61010-2-101:2015 (EN 61010-2-101:2017)	Safety requirements for electrical equipment for measurement, control and laboratory use; Particular requirements
14	EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements Part 1: General requirements
15	EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment
16	IEC 60068-2-64:2008	Environmental Testing-Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance
17	EN 62304:2006	Medical device software - Software life cycle processes
18	EN 62366:2008	Medical devices - Application of usability engineering to medical devices

No.	Title of standards	Contents
19	CLSI EP09-A2:2002	Method comparison and bias estimation using patient samples; Approved guideline
20	CLSI EP05-A2 :2004	Evaluation of precision performance of quantitative measurement methods; Approved guideline
21	CLSI EP06-A: 2003	Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
22	CLSI EP07-A2:2005	Interference Testing in Clinical Chemistry
23	ISO 7000:2004	Graphical symbols for use on equipment – Index and synopsis



## **Attachment #2. Product Code**

#	Product Type	Reference No.	Basic UDI
1	Meter	INFM02A	880911590IGM0002BAS99
2	Strip	INFSS02A	880911590IGM0002BSA25C8
3	Strip	INFS02A	880911590IGM0002BSA50C7
4	Control Solution	INFC02A	880911590IGM0002CSU3

