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
Website: www.osanghc.com

EU Declaration of Conformity

Common Name:	**Blood Glucose Monitoring System for Self-Testing**
Trade Name:	**endire**
Model Name:	**IGM-1001C**
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 inclusing related control materuals
Conformity Assessment Route:	**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
Number of EC Certificate:	V1 001395 0018 Rev.04
Date of Issue:	May 18th, 2022
Expire date of the Certificate:	May 26th, 2025
Valid From:	May 18th, 2022
Manufacturer:	**OSANG Healthcare Co., Ltd.** 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea Tel.: +82-31-460-0300 Fax: +82-31-460-0401
SRN	
Notified Body:	**TÜV SÜD PRODUCT SERVICE GmbH** Ridlerstr. 65, 80339 München, Germany ID/Number of Notified Body: 0123
EU Representative:	**Obelis S.A.** Bd. Général Wahis 53, 1030 Brussels Belgium Phone: +32 2 732 5954 Fax: +32 2 732 6003
Attachments:	1. List of applied standards 2. Basic UDI and Product Code

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: May 18th, 2022

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

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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

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No.	Title of standards	Contents
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 62366:2007	Medical devices - Application of usability engineering to medical devices
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

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Attachment #2. Basic UDI and Product Code

#	Product Type	Reference No.	Basic UDI
1	Meter	INFM001AG	880911590IGM1001CDS9Z
2	Strip	INFS001AG	880911590IGM1001SANBW
3	Control Solution	INFC001AG	880911590IGM1001CSNB4
		INFCL001AG	880911590IGM1001CLNAF
		INFCN001AG	880911590IGM1001CNNAM
		INFCH001AG	880911590IGM1001CHNA3