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:	**GluNEO H**
Model Name:	**OG-SH01-GH**
Basic UDI-DI	**880911590OGSH01GH42**
Product Reference No.:	**Included in "Attachment #2"**
Classification:	**Class C** Rule 4(a) in ANNEX VIII
Conformity Assessment Route:	**Annex IX Chapter I and III** **Annex IX Chapter II, Section 4 and 5.1**
Intended Purpose	The GluNEO H Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use only) of layperson including diabetic patients, as an aid to monitor the effectiveness of diabetes management. The GluNEO H Blood Glucose Monitoring System should not be used for the diagnosis of diabetes. The GluNEO H Blood Glucose Monitoring System is used for the quantitative measurement of the glucose level in fresh capillary whole blood samples drawn from fingertips, ventral palm, dorsal hand, forearm and upper arm.
Number of EC Certificate:	IVDR 811093
Valid From:	2025-08-27
Expire date of the Certificate:	2030-08-26
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: KR-MF-000032605
Authorized Representative	**Obelis S.A.** Bd. Général Wahis 53, 1030 Brussels Belgium Phone: +32 2 732 5954 Fax: +32 2 732 6003 SRN: BE-AR-000000106
Notified Body:	**BSI Group The Netherlands B.V** Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands ID/Number of Notified Body: 2797
Attachments:	1. List of applied standards 2. Product Codes and Refernece List

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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 in “Attachment #1”.

Place: Anyang-si, Republic of Korea Date: Aug 30th, 2025

YoungGyun Kim / PRRC
OSANG Healthcare Co., Ltd.

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Attachment #1. List of applied standards and guidance

No.	Title of standards	Contents
1	**EN ISO 13485:2016**	Medical devices – Quality management system – Requirements for regulatory purpose
2	**EN ISO 14971:2019**	Medical devices - Application of risk management to medical devices
3	**EN 61010-1:2010/A1:2019**	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
4	**EN IEC 61010-2-101:2022**	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
5	**EN IEC 61326-1:2021**	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
6	**EN IEC 61326-2-6:2021**	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
7	**EN 62366-1:2015+A1:2020**	Medical devices - Application of usability engineering to medical devices
8	**EN ISO 15197:2015**	In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
9	**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
10	**EN ISO 15223-1:2021**	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
11	**EN ISO 18113-1:2024**	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
12	**EN ISO 18113-4:2024**	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing
13	**EN ISO 18113-5:2024**	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing
14	**EN ISO 23640:2015**	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
15	**EN 62304:2006/AC:2015**	Medical device software - Software life-cycle processes
16	**IEC 60068-2-64:2008**	Environmental Testing-Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance
17	**CLSI EP25-A**	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline

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No.	Title of standards	Contents
18	**CLSI EP06-A**	Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
19	**ASTM D4169:2022**	Standard Practice for Performance Testing of Shipping Containers and Systems
20	**MDCG 2022-2**	Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs)
21	**EN ISO 20916:2024**	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice

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Attachment #2. Reference List

Rerefence No. (Cat. No.)	Configuration	Description
OG-SH01-GH	Meter, lancing device[1)], lancets[2)] (10EA), strips (10T)	Full-set system
OG-SH01-GH-1	Meter	Included in pouch with logbook
OG-SH01-GHM	Meter	Not in pouch and no logbook
OG-SH01-GH-2	Meter, lancing device[1)], lancets[2)] (10EA)	Full-set system excluding strips
OG-SH01-GHS	50 strips (50T / 1 bottle)	To be distributed individually
OG-SH01-GHS-3	100 strips (50T / 2 bottles)	To be distributed individually
OG-SH01-GHC-1	Control solution – Level 1 (1 bottle)	To be distributed individually
OG-SH01-GHC-2	Control solution – Level 2 (1 bottle)	To be distributed individually

Our declaration of conformity does not apply to the lancing device[1)] and lancets[2)] for following reasons.

1) Lancing device is a class I medical device regulated under MDR (2017/745). It is a medical accessory supplied by a third manufacturer (SterliLance Medical (Suzhou) Inc.(SRN: CN-MF-000002860)) and its declaration of conformity has been confirmed. The third party's declaration of conformity is retained for rationale.

2) Lancet is a Class IIa medical device regulatd under MDR (2017/745). It is a medical accesorry supplied by a third manufacturer (SterliLance Medical (Suzhou) Inc.(SRN: CN-MF-000002860)) and its EU Quality Management System Certificate (MDR) has been confirmed. The MDR certificate (Certificate No. G10 093119 0001) is retained for rationale.