OHC
OSANG HEALTHCARE

Declaration of Conformity

Manufacturer's Name:	**OSANG Healthcare Co., Ltd.**
Address:	132, Anyangcheondong-ro, Dongan-Gu Anyang-si, Gyeonggi-do, 14040, Republic of Korea *Tel.: +82-31-460-0300 Fax: +82-31-460-0401*
EC-Representative:	**Obelis S.A.**
Address:	Bd. Général Wahis 53, 1030 Brussels, Belgium

Declares that the product:

Product:	**Blood Glucose Monitoring System for Self-Testing** **GluNEO (IGM-1001C)**
Classification:	**List B According to Annex II of IVDD 98/79/EC** Blood glucose measuring systems for self-testing including related control materials.
Conformity assessment Route:	**Annex IV without section 4 and 6 of the IVDD 98/79/EC (Full Quality Assurance)**

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer and manufacturer is exclusively responsible for the declaration of conformity.

Notified Body : **TÜV SÜD PRODUCT SERVICE GmbH**
Ridlerstr. 65, 80339 München, Germany

ID/Number of Notified Body: 0123

Number of EC Certificate	**:**	**V1 001395 0018 Rev.00**
Issue date	**:**	**December 06, 2019**
Expiry date	**:**	**October 14, 2023**
Place	**:**	**Anyang-si, Korea**
Valid From	**:**	**December 06, 2019**

Attachment #1. Products, Attachment #2. List of applicable standards

Signature: _____

Dong Hyun, Lee

CEO of OSANG Healthcare Co., Ltd

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Attachment #1. Products

Blood Glucose Monitoring System for Self-testing

- Blood Glucose Test Meter
- Blood Glucose Test Strip
- Blood Glucose Control Solution (Option)

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Attachment #2. List of applicable 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

No.	Title of standards	Contents
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 62366:2007**	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