

Declaration of Conformity

Manufacturer's Name: OSANG Healthcare Co., Ltd.

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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
endire (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

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