

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

## IVDR 793282 R000

**Manufacturer:** Osang Healthcare Co., Ltd.

**Address:**

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Dongan-gu  
Anyang-si  
Gyeonggi-do  
14040  
Republic of Korea

**Single Registration Number:** KR-MF-000032605

**EU Authorised Representative:** Obelis s.a.

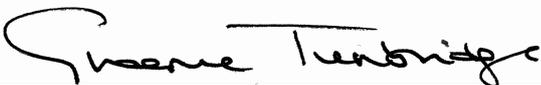
**Address:**

Boulevard Général Wahis 53  
1030 Brussels  
Belgium

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-10-25**

Current Issue Date: **2024-10-25**

Starting Validity Date: **2024-10-25**

Expiry Date: **2029-10-24**

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### Device Schedule:

#### Intended Purpose:

##### Meter and Test Strips

The GlucoLAB AutoCoding S 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 GlucoLAB AutoCoding S Blood Glucose Monitoring System should not be used for the diagnosis of diabetes. The GlucoLAB AutoCoding S 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.

##### Control solution

The GlucoLAB AutoCoding S control solution is used for performing quality control tests on the GlucoLAB AutoCoding S meter and GlucoLAB AutoCoding S test strips as part of self-testing to ensure that the meter and test strips are working together properly for the accurate measurement of glucose in your blood.

**Risk Classification:** Class C self-test

**Type** (Codes as per (EU) 2017/2185): IVR 0602

**Basic UDI-DI:** 880911590OGSX01LB9M

Device Name	Model
GlucoLAB AutoCoding S Blood Glucose Monitoring System (OG-SX01-LB)	OG-SX01-LB: Meter, lancing device, lancets (10EA), strips (10T)
	OG-SX01-LB-1: Meter (Included in pouch with logbook)
	OG-SX01-LBM: Meter (Not in pouch and no logbook)
	OG-SX01-LB-2: Meter, lancing device, lancets (10EA)

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Device Name	Model
GlucolAB AutoCoding S Blood Glucose Monitoring System (OG-SX01-LB)	OG-SX01-LBS: 50 strips (50T / 1 bottle)
	OG-SX01-LBS-1: 50 strips (25T / 2 bottles)
	OG-SX01-LBS-2: 25 strips (25T / 1 bottle)
	OG-SX01-LBS-3: 100 strips (50T / 2 bottles)
	OG-SX01-LBC-1: Control solution - low concentration (1 bottle)
	OG-SX01-LBC-2: Control solution - normal concentration (1 bottle)
	OG-SX01-LBC-3: Control solution - high concentration (1 bottle)

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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
Current	30001798	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.