EU Technical Documentation Assessment Certificate

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

IVDR 811093 R000

Manufacturer: Osang Healthcare Co., Ltd.

Address:
132 Anyangcheondong-ro
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: **2025-08-27**

Current Issue Date: **2025-08-27**

Starting Validity Date: **2025-08-27**

Expiry Date: **2030-08-26**

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Device Schedule:

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.

Risk Classification: Class C self-test

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

Basic UDI-DI: 880911590OGSH01GH42

Device Name	Model
GluNEO H Blood Glucose Monitoring System (OG-SH01-GH)	OG-SH01-GH: Meter, lancing device, lancets (10EA), strips (10T)
	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, lancets (10EA)
	OG-SH01-GHS: 50 strips (50T / 1 bottle)
	OG-SH01-GHS-3: 100 strips (50T / 2 bottles)
	OG-SH01-GHC-1: Control solution – Level 1 (1 bottle)
	OG-SH01-GHC-2: Control solution – Level 2 (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	30192736	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.

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