



# EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

**No. V1 001395 0018 Rev. 04**

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

132, Anyangcheondong-ro, Dongan-gu  
Anyang-si, Gyeonggi-do 14040  
REPUBLIC OF KOREA

**Product Category(ies): Blood glucose measuring systems for self testing  
Products for determination of PSA, Chlamydia,  
HLA tissue groups and Self tests for cholesterol/  
HbA1c**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V1 001395 0018 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:V1_001395_0018_Rev.04)

**Report no.:** 74961791

**Valid from:** 2022-05-18

**Valid until:** 2025-05-26

**Date,** 2022-05-18

Christoph Dicks  
Head of Certification/Notified Body



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**Model(s):** See attachment  
**Facility(ies):** OSANG Healthcare Co., Ltd.  
 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do  
 14040, REPUBLIC OF KOREA

## Blood Glucose Monitoring System

- Blood Glucose Meter
- Blood Glucose Test Strip
- Blood Glucose Control Solution

Model	Brand
IGM-0002A	EASYGLUCO
IGM-0005A	FINETEST
IGM-0016B	EASYGLUCO Auto-coding
IGM-0017A	FINETEST Auto-coding
IGM-0017B	FINETEST Auto-coding premium
IGM-0021	ELEMENT/EVOLUTION PLUS
IGM-0022	GLUCOLAB Auto-coding
IGM-0028A/B	Healthpro
IGM-0028B	Healthpro-X1
IGM-0028C	Gluco Check Excellent
IGM-0030A/B/C	Finetest Platinum/Medi-Check/INFINITY®
IGM-1001C	GluNEO/ELEMENT NEO/endire
IGM-1001A	Oh'Care
IGM-1001D	GluNEO Smart/BLE Smart
IGM-1003A	GluNEO Lite/EASYGLUCO Pro/adia/G-TECH Free Lite/Oh'Care Lite/EXAMEDIN® Fast
IGM-1003B	Finetest Lite/CURO G6
IGM-1003E	GluNEO plus/BasuGold
IGM-1003F	GluNEO Lite Smart/G-TECH Lite Smart/Oh'Care Lite Smart/EXAMEDIN® Fast Pro
IGM-1003G	Finetest Lite Smart/CURO G6s
IGM-1007A	GluNEO M3
IGM-1007B	GluNEO S3



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## Self HbA1c Test and Blood Glucose Monitoring System

- HbA1c Analyzer
- Test Cartridge
- Check Cartridge
- HbA1c Control Solution
- Glucose Test Module

Model	Brand
IGM-0023	CLOVER A1c Self

## Lipid Profile and Glucose Measuring System

- Lipid Profile and Glucose Test Meter
- Total Cholesterol Test Strip
- HDL-Cholesterol Test Strip
- Triglyceride Test Strip
- Blood Glucose Test Strip
- Lipid Profile Test Strip
- Total Cholesterol Control Solution
- HDL-Cholesterol Control Solution
- Triglyceride Control Solution
- Blood Glucose Control Solution
- Lipid Profile Check Strip

Model	Brand
ILM-0001A	LipidPro, ELEMENT Multi, CURO L5

## Products for determination of tumor markers(PSA)

Model	Brand
IIM-0001PS	SelexOn PSA
IIM-0001FP	SelexOn Free PSA



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### Products for determination of infection markers for Chlamydia

Model	Brand
IFMR-03	Multiplex Real-time PCR kit for CT(Chlamydia trachomatis) NG (Neisseria gonorrhoeae) and UU (Ureaplasma urealyticum)

### Determining the HLA tissue groups

Model	Brand
IFMR-08	GeneFinder HLA-B*27 RealAmp kit
IFMR-09	GeneFinder HLA-B*51 RealAmp kit
IFMR-10	GeneFinder HLA-ABDR RealAmp kit
IFMR-20	GeneFinder HLA-ABCDRB1DQ RealAmp Kit
IFMR-22	GeneFinder HLA-B*57:01 RealAmp Kit