

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. 00

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. See also notes overleaf.

Report no.: 74954729

Valid from: 2019-12-06

Valid until: 2023-10-14

Date. 2019-12-06

C.Dh

Christoph Dicks
Head of Certification/Notified Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

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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



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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