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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

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



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

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



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

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



EC Certificate

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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

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



Product Service

Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 001395 0020 Rev. 00

Manufacturer:

OSANG Healthcare Co., Ltd.

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

This Confirmation Statement V1 001395 0018 Rev. 04
is only valid in combination
with the following
EC Certificate (IVDD):

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (IVDD). It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2022 or later.

The conditions laid down in Article 110 (3) of Regulation (EU) 2017/746 on in vitro diagnostic medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:VCQ 001395 0020 Rev. 00

Report No.: 72446663

Valid until: 2025-05-26

Marta Carnielli
Head of Certification IVD

Issue Date: 2023-10-18

**Confirmation Statement on validity of EC Certificate (IVDD)**

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 001395 0020 Rev. 00

Product Blood glucose measuring systems for self testing,
Category(ies) Products for determination of Chlamydia, HLA tissue groups
 : and Self tests for Cholesterol/HbA1c
Description Reduction of models : Products for determination
 of Change: of tumor markers (PSA)

Reduction of models from BGMS

Following models are remaining valid:

Model(s):**Blood Glucose Monitoring System**

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

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



Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 001395 0020 Rev. 00

Description of Change: 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



Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 001395 0020 Rev. 00

Description of Change: 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

Supplementary information to AR120 835204

Non-significant changes approved after the 26th May 2022 as per the Transitional Provisions of IVDR Article 110.3

Issued to:

OSANG Healthcare Co., Ltd.
 132, Anyangcheondong-ro, Dongan-gu
 Anyang-si, Gyeonggi-do 14040
 REPUBLIC OF KOREA

Date: 19 February 2026

Changes Approved:

Date	Reference Number	Action
19 February 2026	30540222	Transfer of appropriate surveillance to BSI per Regulation EU 2024/1860 of devices: <ul style="list-style-type: none"> - Multiplex Real-time PCR kit For CT (Chlamydia trachomatis) NG (Neisseria gonorrhoeae) And UU (Ureaplasma urealyticum) (IFMR-03) - GeneFinder™ HLA-B*51 RealAmp Kit (IFMR-09) - GeneFinder™ HLA-ABCDRB1DQ RealAmp kit (IFMR-20) - GeneFinder™ HLA-B*57:01 RealAmp kit (IFMR-22) - GeneFinder™ HLA-ABDR RealAmp Kit (IFMR-10) - CLOVER A1c Self System (IGM-0023) - EASYGLUCO Auto-coding Blood Glucose Monitoring System (IGM-0016B) - FINETEST Auto-coding Premium Blood Glucose Monitoring System (IGM-0017B) - Finetest Lite Blood Glucose Monitoring System (IGM-1003B) - GlucoCheck Excellent Blood Glucose Monitoring System (IGM-0028C) - adia Blood Glucose Monitoring System (IGM-1003A) - Finetest Lite Smart Blood Glucose Monitoring System (IGM-1003G)

Date	Reference Number	Action
19 February 2026	30540222	<ul style="list-style-type: none"> - GluNEO Lite Blood Glucose Monitoring System (IGM-1003A) - Oh'Care Lite Blood Glucose Monitoring System (IGM-1003A) - Examedin® FAST Blood Glucose Monitoring System (IGM-1003A) - GluNEO Plus Blood Glucose Monitoring System (IGM-1003E) - Healthpro-X1 Blood Glucose Monitoring System (IGM-0028B) - GLUCOLAB Auto-coding Blood Glucose Monitoring System (IGM-0022) - ELEMENT Blood Glucose Monitoring System (IGM-0021) - GluNEO Blood Glucose Monitoring System (IGM-1001C) <p>Original NB Certificate Number: V1 001395 0018 Rev. 04 Confirmation Statement on validity of EC Certificate (IVDD): VCQ 001395 0020 Rev. 00</p>

19 February 2026

Osang Healthcare Co., Ltd.
132 Anyangcheondong-ro
Dongan-gu
Anyang-si
Gyeonggi-do
14040
Republic of Korea

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

The transitional provisions specified in IVDR Article 110(3) (as amended by (EU) 2024/1860) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) or under IVDR Article 110(3), as applicable, and as per the guidance provided in MDCG 2020-3/MDCG 2022-6.

The related certificate specified below continues to remain valid and devices can be placed on the market based on this certificate as long as the manufacturer complies with the conditions specified in Section 3c of Article 120 of MDR or in Section 3c of Article 110 of IVDR, as applicable.

Original certificate number	BSI reference number	Directive and Annex	Reference Number	Changes approved
V1 001395 0018 Rev.04	AR120 835204	98/79/EC Annex IV excluding Sections 4 and 6	30540222	Transfer of appropriate surveillance to BSI per Regulation EU 2024/1860 of devices: - Multiplex Real-time PCR kit For CT (Chlamydia trachomatis) NG (Neisseria gonorrhoeae) And UU (Ureaplasma urealyticum) (IFMR-03) - GeneFinder™ HLA-B*51 RealAmp Kit (IFMR-09) - GeneFinder™ HLA-ABCDRB1DQ RealAmp kit (IFMR-20) - GeneFinder™ HLA-B*57:01 RealAmp kit (IFMR-22) - GeneFinder™ HLA-ABDR RealAmp Kit (IFMR-10) - CLOVER A1c Self System (IGM-0023)

Original certificate number	BSI reference number	Directive and Annex	Reference Number	Changes approved
V1 001395 0018 Rev.04	AR120 835204	98/79/EC Annex IV excluding Sections 4 and 6	30540222	<ul style="list-style-type: none"> - EASYGLUCO Auto-coding Blood Glucose Monitoring System (IGM-0016B) - FINETEST Auto-coding Premium Blood Glucose Monitoring System (IGM-0017B) - Finetest Lite Blood Glucose Monitoring System (IGM-1003B) - GlucoCheck Excellent Blood Glucose Monitoring System (IGM-0028C) - adia Blood Glucose Monitoring System (IGM-1003A) - Finetest Lite Smart Blood Glucose Monitoring System (IGM-1003G) - GluNEO Lite Blood Glucose Monitoring System (IGM-1003A) - Oh'Care Lite Blood Glucose Monitoring System (IGM-1003A) - Examedin® FAST Blood Glucose Monitoring System (IGM-1003A) - GluNEO Plus Blood Glucose Monitoring System (IGM-1003E) - Healthpro-X1 Blood Glucose Monitoring System (IGM-0028B) - GLUCOLAB Auto-coding Blood Glucose Monitoring System (IGM-0022) - ELEMENT Blood Glucose Monitoring System (IGM-0021) - GluNEO Blood Glucose Monitoring System (IGM-1001C) <p>Original NB Certificate Number: V1 001395 0018 Rev. 04 Confirmation Statement on validity of EC Certificate (IVDD): VCQ 001395 0020 Rev. 00</p>

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices