EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1036863-1

Manufacturer:
Diagnosis S.A.
ul. Gen. Wladyslawa Andersa 38 A
15-113 Bialystok
Poland

Products:
- Fecal Occult Blood Self Testing Devices
- HCG Rapid Self Testing Devices
- LH Rapid Self Testing Devices
- FSH Rapid Self Testing Devices
- Drug of Abuse Urine Self Testing Devices
- Drug of Abuse Saliva Self Testing Devices
- Helicobacter Pylori Self Testing Devices
- Sperm Concentration Test
- Blood Glucose Monitoring Systems for Self Testing
- Blood Glucose Test Strips for Self Testing
- Blood Glucose Meters for Self Testing
- Control Solutions for Self-Testing
- PSA Self Testing Devices

Replaces Certificate number HL 1036863-1, dated 2022-03-11

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 84958412-30

Effective date: 2022-05-25

Expiry date: 2025-05-26

Issue date: 2022-05-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Sebastian Mniszek
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1036863-1

Manufacturer:
Diagnosis S.A.
ul. Gen. Wladyslawa Andersa 38 A
15-113 Bialystok
Poland

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Diagnosis S.A. ul. Gen. Wladyslawa Andersa 38 A 15-113 Bialystok Poland	Activity: Administration.
/02	Diagnosis S.A. ul. Przemysłowa 8 16-010 Wasilków Poland	Activity: Production and quality control of in-vitro diagnostic rapid tests, blood glucose monitoring systems for self-testing, control solutions for self-testing, blood glucose tests strips for self-testing and glucose meters for self-testing.

Report No.: 84958412-30

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Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1036863-1

Manufacturer: Diagnosis S.A.
ul. Gen. Wladyslawa Andersa 38 A
15-113 Bialystok
Poland

The scope of certification includes the following manufacturing sites:

/03 Diagnosis S.A.
ul. Serwisowa 13
15-113 Białystok
Poland

Activity: Production and final inspection of Fecal Occult Production, Product release of Fecal Occult Blood Self Testing Devices, HCG Rapid Self Testing Devices, LH Rapid Self Testing Devices, FSH Rapid Self Testing Devices, Drug of Abuse Urine Self Testing Devices, Drug of Abuse Saliva Self Testing Devices, Helicobacter Pylori Self Testing Devices, Sperm Concentration Test, Blood Glucose Monitoring Systems for Self Testing, Blood Glucose Test Strips for Self Testing, Blood Glucose Meters for Self Testing, Control Solutions for Self-Testing, PSA Self Testing Devices.

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