

# EC Certificate

**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. Władysława Andersa 38 A  
15-113 Białystok  
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 EC Certificate number HL 1036863-1, dated 2021-04-14

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.: 84952315-130

Effective date: 2021-05-04

Expiry date: 2022-03-11

Issue date: 2021-05-04



Benia Świątko  
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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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The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Diagnosis S.A. ul. Gen. Władysława Andersa 38 A 15-113 Białystok Poland	Activity: Administration.
/02	Diagnosis S.A. ul. Przemysłowa 8 16-010 Wasilków Poland	Activity: Production and final inspection of in-vitro diagnostic rapid tests, blood glucose monitoring systems for self-testing with control solutions, blood glucose test strips, blood glucose meters. Production and final inspection of blood glucose meter for self-testing.
/03	Diagnosis S.A. ul. Przemysłowa 1 16-010 Wasilków Poland	Activity: Production of in-vitro diagnostic rapid tests, blood glucose monitoring systems for self-testing with control solutions, blood glucose test strips, blood glucose meters.

Report No.: 84952315-130

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