EC Certificate

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

Registration No.: HL 60118565 0001

Report No.: 26300376 001

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

Products: IVD self-testing devices

(see attachment for products and sites included)
Replaces Certificate, Registration No.: HL 60110987 0001

Expiry Date: 2022-03-11

The Notified Body hereby declares that the requirements of Annex IV, excluding section 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.

Effective Date: 2017-04-18

Date: 2017-04-18

Notified Body

Maciej Sciera

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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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Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60118565 0001
Report No.: 26300376 001

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

Products included:

IVD self-testing devices:
- 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
- Allergen Specific Self-Testing Devices
- Sperm Concentration Test

Annex II, List B Devices:
- 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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Maciej Sciera

Date: 2017-04-18

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60118565 0001
Report No.: 26300376 001

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

Site included:

Diagnosis S.A.
ul. Przemyslowa 8
16-010 Wasilkow
Poland

Storage, packaging, incoming and final inspection and shipment

Notified Body

Maciej Sciera

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2017-04-18