TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

(see attachment for the scope and sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2017-04-18
Certificate Registration No.:	SX 60117867 0001
An audit was performed. Report No.:	26300376 001
This Certificate is valid until:	2019-03-30

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2017-04-18

Maciej Sciera

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60117867 0001
Report No.: 26300376 001

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

Scope:

Design and development, manufacture and distribution of in-vitro diagnostic rapid tests Blood Glucose Monitoring Systems for self-testing.
Manufacture, distribution and servicing of diagnostic medical devices as follows: Blood Pressure Meters, Digital Thermometers, Infrared Thermometers, ECG moitoring, ECG signal acquisition devices, ECG viewing application - software and Nebulizers with related accessories as well as manufacture and distribution of invasive sample collection devices.

Sites included:

Diagnosis S.A.
ul. Przemyslowa 8
16-010 Wasilkow, Poland
Storage of final products, distribution and shipment. Incoming inspection, completion and final packaging, quality control and servicing.

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2017-04-18

Maciej Sciera