

# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 1036863-1

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

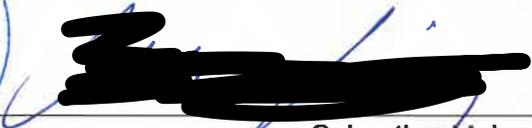
Scope: Design and development, production and distribution of in-vitro diagnostic rapid tests and blood glucose monitoring systems for self-testing, blood glucose tests strips for self-testing, glucose meters for self-testing, control solutions for self-testing.

Production, distribution and servicing of blood pressure monitors, digital thermometers, infrared thermometers, mercury free clinical thermometers, ECG monitors, ECG signal acquisition devices, ECG viewing application - software, nebulizers with related accessories and fingertip pulse oximeters as well as production and distribution of invasive sample collection devices.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84958412-30  
Effective date: 2022-04-15  
Expiry date: 2025-04-15  
Issue date: 2022-04-15



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



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15-113 Bialystok  
Poland

The scope of certification includes for following additional sites:

No.	Facility	Scope
/01	Diagnosis S.A. ul. Gen. Wladyslawa Andersa 38 A 15-113 Bialystok Poland	Administration.
/02	Diagnosis S.A. ul. Przemysłowa 8 16-010 Wasilków Poland	Incoming inspection, quality control and servicing, storage of products: blood pressure meters, digital thermometers, infrared thermometers, mercury free clinical thermometers, lancets, ultrasonic nebulizers, compressor nebulizers, mesh nebulizers, accessories for nebulizers, fingertip pulse oximeters, ECG monitors, ECG Signal acquisition devices, ECG viewing application - software; 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. Production of blood glucose meters for self-testing, blood glucose tests strips for self-testing, control solutions for self-testing.

Report No.: 84958412-30  
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Mniszek  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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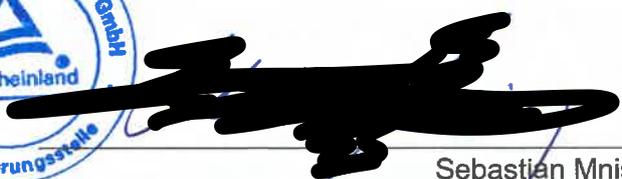
Organization: Diagnosis S.A.  
ul. Gen. Wladyslawa Andersa 38 A  
15-113 Bialystok  
Poland

The scope of certification includes for following additional sites:

- |     |   |   |
|-----|---|---|
| /03 | Diagnosis S.A.<br>ul. Przemysłowa 1<br>16-010 Wasilków<br>Poland        | Storage of goods; blood pressure meters, digital thermometers, infrared thermometers, mercury free clinical thermometers, lancets, ultrasonic nebulizers, compressor nebulizers, mesh nebulizers, accessories for nebulizers, fingertip pulse oximeters, ECG monitors, ECG Signal acquisition devices, ECG viewing applications - software; in-vitro diagnostic rapid tests, blood glucose monitoring systems for self-testing, blood glucose test strips for self-testing, control solutions for self-testing.   |
| /04 | Diagnosis S.A.<br>ul. Porosły 84B<br>16-070 Choroszcz-Porosły<br>Poland | Storage of final products, distribution of blood pressure meters, digital thermometers, infrared thermometers, mercury free clinical thermometers, lancets, ultrasonic nebulizers, compressor nebulizers, mesh nebulizers, accessories for nebulizers, fingertip pulse oximeters, ECG monitors, ECG Signal acquisition devices, ECG viewing applications - software; 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. |

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**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 1036863-1

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

The scope of certification includes for following additional sites:

/05 **Diagnosis S.A.**  
ul. Serwisowa 13  
15-113 Białystok  
Poland

Completing and final packaging, storage, final quality of blood pressure meters, digital thermometers, infrared thermometers, mercury free clinical thermometers, lancets, ultrasonic nebulizers, compressor nebulizers, mesh nebulizers, accessories for nebulizers, fingertip pulse oximeters, ECG monitors, ECG Signal acquisition devices, ECG viewing application – software, in-vitro diagnostic rapid tests, blood glucose monitoring systems for self-testing, control solutions for self-testing, blood glucose test strips for self-testing and glucose meters for self-testing.

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