

# Certificate

## Quality Management System

**EN ISO 13485:2016**

**EN ISO 13485:2016/AC:2018**

**EN ISO 13485:2016/A11:2021**

Registration No.: SX 1036863-1

Certificate Holder: 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 for fertility and pregnancy detection.  
Design and development, manufacture and distribution of blood glucose test strips and blood test strips controls for self-testing. Design and development, manufacture, distribution and servicing of blood glucose meters for self-testing.  
Manufacture, distribution and servicing of lancing devices, non-invasive oscillometric blood pressure gauges, ECG monitors, ECG signal acquisition devices, ECG viewing application - software, contact and non-contact digital thermometers and nebulizers systems with related accessories, blood pressure cuffs.  
Manufacture and distribution of lancets without safety system.

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.: 84982534-20

Effective date: 2025-06-17

Expiry date: 2028-04-15

Issue date: 2025-06-17

Replaces certificate SX 1036863-1 issued 2025-04-15



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This certificate can be validated on <https://www.certipedia.com>

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The scope of certification also covers the following 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	Design and development, manufacture, incoming inspection, completing and final packaging, storage of products and final quality control of blood glucose test strips and blood test strips controls for self-testing and in-vitro diagnostic rapid tests for fertility and pregnancy detection. Design and development, manufacture, incoming inspection, completing and final packaging, storage of products, final quality control and servicing of blood glucose meters for self-testing. Manufacture, servicing, incoming inspection, completing and final packaging, storage and final quality control of products: lancing devices, non-invasive oscillometric blood pressure gauges, ECG monitors, ECG signal acquisition devices, ECG viewing application - software, contact and non-contact digital thermometers and nebulizers systems with related accessories, blood pressure cuffs. Manufacture, incoming inspection, completing and final packaging, storage and final quality control of lancets without safety system.
/03	Diagnosis S.A. ul. Przemysłowa 1 16-010 Wasilków Poland	Storage of products: in-vitro diagnostic rapid tests for fertility and pregnancy detection, blood glucose meters for self-testing, blood glucose test strips and blood test strips controls for self-testing, non-invasive oscillometric blood pressure gauges, contact and non-contact digital thermometers, ECG monitors, ECG signal acquisition devices, ECG viewing application - software, lancing device, lancets without safety system and nebulizers with related accessories, blood pressure cuffs.
/04	Diagnosis S.A. ul. Zakładowa 8 16-010 Wasilków Poland	Incoming inspection, distribution and storage of final products: in-vitro diagnostic rapid tests for fertility and pregnancy detection, blood glucose meters for self-testing, blood glucose test strips and blood test strips controls for self-testing, non-invasive oscillometric blood pressure gauges, contact and non-contact digital thermometers, ECG monitors, ECG signal acquisition devices, ECG viewing application - software, lancing device, lancets without safety system and nebulizers with related accessories, blood pressure cuffs.

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