

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. Władysława Andersa 38 A
15-113 Białystok
Poland

Scope: Design and development, manufacture, and distribution of in-vitro diagnostic rapid tests for fertility and pregnancy detection, fecal occult blood detection, prostate-specific antigen (PSA) detection, drugs of abuse detection, and *Helicobacter pylori* 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.: 84977388-20

Effective date: 2025-04-16

Expiry date: 2028-04-16

Issue date: 2025-04-15

Replaces certificate SX 1036863 issued 2022-04-15

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. Władysława Andersa 38 A 15-113 Białystok Poland	Administration.
/02	Diagnosis S.A. ul. Przemysłowa 8 16-010 Wasilków Poland	<p>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, fecal occult blood detection, prostate-specific antigen (PSA) detection, drugs of abuse detection, and <i>Helicobacter pylori</i> detection.</p> <p>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.</p> <p>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.</p> <p>Manufacture, incoming inspection, completing and final packaging, storage and final quality control of lancets without safety system.</p>

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15-113 Białystok
Poland

The scope of certification also covers the following sites:

/03

Diagnosis S.A.
ul. Przemysłowa 1
16-010 Wasilków
Poland

Storage of products; in-vitro diagnostic rapid tests for fertility and pregnancy detection, fecal occult blood detection, prostate-specific antigen (PSA) detection, drugs of abuse detection, and *Helicobacter pylori* 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. Porosły 84B
16-070 Choroszcz-Porosły
Poland

Distribution and storage of final products; in-vitro diagnostic rapid tests for fertility and pregnancy detection, fecal occult blood detection, prostate-specific antigen (PSA) detection, drugs of abuse detection, and *Helicobacter pylori* 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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