

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1036863-1

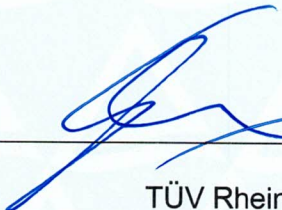
Organization: Diagnosis S.A.
ul. Gen. Władysława Andersa 38 A
15-113 Białystok
Poland

Scope: Design and development, production and distribution of in-vitro diagnostic rapid tests and blood glucose monitoring systems for self-testing with control solutions, blood glucose test strips, blood glucose meters. 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.: 84952934-20
Effective date: 2021-05-24
Expiry date: 2022-04-15
Issue date: 2021-05-24




Daniel Swiatko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1036863-1

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

The scope of certification includes the following additional 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	Incoming inspection, completing and final packaging, quality control and servicing, storage of final 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 with control solutions, blood glucose test strips, blood glucose meters. Production of blood glucose meter for self-testing.

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Daniel Świątko
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Organization: Diagnosis S.A.
ul. Gen. Władysława Andersa 38 A
15-113 Białystok
Poland

The scope of certification includes the following additional sites:

/03 Diagnosis S.A.
ul. Przemysłowa 1
16-010 Wasilków
Poland

Incoming inspection, storage of goods; blood pressure meters, digital thermometers, infrared thermometers, mercury free clinical thermometers, lancets, ultrasonic nebulizers, mesh nebulizers, compressor 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 with control solutions, blood glucose test strips, blood glucose meters.

/04 Diagnosis S.A.
ul. Porosły 84B
16-070 Choroszcz
Poland

Storage of final products, distribution and shipment of blood pressure meters, digital thermometers, infrared thermometers, mercury free clinical thermometers, lancets, ultrasonic nebulizers, compressor 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 with control solutions, blood glucose test strips, blood glucose meters.

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