

Certificate

Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 1886935-1

Certificate Holder: ANALITYK Ewa Kowalczyk
ul. Romera 10 lok. B9
02-784 Warszawa
Poland

Scope: Distribution of in vitro diagnostic reagents, instruments and related consumables and software for next-generation sequencing (NGS), polymerase chain reaction (PCR) and genotyping used in the field of genetic testing. Installation and servicing of in vitro diagnostic instruments for next-generation sequencing (NGS), polymerase chain reaction (PCR), and genotyping used in the field of genetic testing.

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.: 84985845-30

Effective date: 2026-07-28

Expiry date: 2029-07-27

Issue date: 2026-07-28

Marta Trzpil

Marta Trzpil
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	ANALITYK Ewa Kowalczyk ul. Romera 10 lok B9 02-784 Warszawa Poland	Administration and distribution of in vitro diagnostic reagents, instruments and related consumables and software for next-generation sequencing (NGS), polymerase chain reaction (PCR), and genotyping used in the field of genetic testing. Installation and servicing of in vitro diagnostic instruments for next generation sequencing (NGS), polymerase chain reaction (PCR), and genotyping used in the field of genetic testing.
/02	ANALITYK Warehouse ul. Surowieckiego 12 02-784 Warszawa Poland	Storage of in vitro diagnostics instruments and related consumables.

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