

This is a translation of the certificate HU15/7647

The management system of

# NORMA Instruments Zrt.

H-1038 Budapest Papírgyár u. 58-59.

has been assessed and certified as meeting the requirements of

## MSZ EN ISO 13485:2016

For the following activities

Development, production and distribution of haematology blood analysis systems and haematology reagents for the in-vitro diagnostic (IVD) market.

This certificate is valid from 12 May 2023 until 28 April 2024 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 29 April 2015

Certified activities performed by additional sites are listed on subsequent pages.



Authorised by  
Andras Tohl

SGS Hungária Kft.  
1124 Budapest, Sirály u. 4.  
t +3613093340 - www.sgs.hu



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



This is a translation of the certificate HU15/7647, continued

# NORMA Instruments Zrt.

## MSZ EN ISO 13485:2016

Issue 4
<b>Sites</b>
NORMA Instruments Zrt. H-1038 Budapest Papírgyár u. 58-59.
Development, production and distribution of haematology blood analysis systems for the in-vitro diagnostic (IVD) market.
NORMA Instruments Zrt. H-1044 Budapest, Ezred u. 2.
Warehousing, packaging and distribution activity in support of Development, production and distribution of haematology blood analysis systems and haematology reagents for the in-vitro diagnostic (IVD) market.



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.





# CERTIFICATE



## EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

### Analyticon Biotechnologies GmbH

#### Scope of certification:

Development, production and distribution of in-vitro diagnostics from the field of urine diagnostics for professional and near-patient applications

Distribution, service and installation of in-vitro-diagnostic analyzers from the field of urine diagnostics.

Distribution of in-vitro diagnostic devices from the field of hematology

Distribution and service of in-vitro-diagnostic analyzers from the field of hematology

#### Certified location:

Am Mühlberg 10, 35104 Lichtenfels, Germany  
(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 51519-R1-00.

Certificate registration no.: 51519-14-02\_EN

Certificate valid from: 2023-03-06

Validity of previous certificate: 2023-03-05

Certificate valid to: 2025-01-10

  
Karin Leicht



DEKRA Certification GmbH, Stuttgart, 2023-03-06





# Annex to the Certificate No. 51519-14-02

valid from 2023-03-06 to 2025-01-10

The following locations/companies belong to the certificate above:

	Headquarters	Scope of certification
	Analyticon Biotechnologies GmbH Am Mühlberg 10 35104 Lichtenfels Germany	see page 1
	at the following locations/at the companies at the following locations	Scopes of certification
1.	Am Teichsberg 10 Lichtenfels-Sachsenberg Germany	Reception, shipping and storage of raw materials, semi-finished goods, finished goods and analyzers from the fields of urine diagnostics and hematology.



*Karin Leicht*

Karin Leicht  
DEKRA Certification GmbH, Stuttgart, 2023-03-06