



CERTIFICATE OF CONFORMITY

quality management system

This certificate confirms
that the quality management system in relation to the processes:

Distribution, maintenance services medical devices and medical devices for in vitro diagnostics and services of the Authorized Representative in Ukraine for manufacturers of medical devices for in vitro diagnostics

carried out by the

**LIMITED LIABILITY COMPANY
"DIALOGUE DIAGNOSTICS"**

Legal address: 04205, Kyiv, Obolonsky ave., bldg. 32, Ukraine
Actual address: 04209, Kyiv, Lebedyn'ska str., bldg. 10, Ukraine
USREOU code 34839344

meets the requirements of the standards

DSTU EN ISO 13485:2018

Medical devices. Quality management systems.
Requirements for regulatory purposes
(EN ISO 13485:2016, IDT; ISO 13485:2016, IDT)
and

ISO 13485:2016

Medical devices – Quality management systems – Requirements for regulatory purposes

The compliance of the certified quality management system with the requirements of specified standards is verified by periodical surveillance audits

Certificate № 064-22
Valid until June 22, 2028.
Version № 3 dated June 23, 2025.
First issued June 23, 2022.




Head of conformity
assessment body
Roman MYKHALKO





HISTORY OF THE CERTIFICATE

Version №	Dated	Description
1	June 23, 2022	First issue.
2	August 02, 2024	The scope of the certificate regarding the activity of "services of the Authorized Representative in Ukraine for manufacturers of medical devices for in vitro diagnostics" has been expanded.
3	June 23, 2025	Re-certified. The scope of the certificate has been stated in a new wording.

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Переклад сертифіката на англійську мову.

№ QMS.000152-2