

CERTIFICATE

on compliance of Quality Management System

Registration Date:

August 02, 2024

No. UA.SM.214-21

Expiry Date: August 01, 2027

First edition: August 04, 2021

**THIS IS TO CERTIFY THAT
QUALITY MANAGEMENT SYSTEM CONCERNING**

**The Design and Development, Manufacture, Storage and Distribution
medical devices for in vitro diagnostics**

was implemented by: XEMA LLC

at the address: Akademika Yefremova St. 23, Kyiv, Ukraine, 03179

**meets the requirements of DSTU EN ISO 13485:2018
(EN ISO 13485:2016, IDT; ISO 13485:2016, IDT); ISO 13485:2016.**

Compliance control of the certified quality management system with the requirements of the specified standard is carried out through supervision, the frequency and procedures of which are regulated by the procedures of the conformity assessment body.

The conformity assessment body UKRMEDCERT LLC, address: str. Drahomanova, building 1-A, office 2, Kyiv, 02059, Ukraine, phone: +38-067-595-02-30, <https://ukrmedcert.org.ua>

Head of CAB



Tetiana SUKHENKO

The validity of a certificate of compliance can be verified in the online Register
<https://ukrmedcert.org.ua> or by phone +38-067-595-02-30.
The original version of this Certificate is issued in Ukrainian.

