

# MANAGEMENT SYSTEM CERTIFICATE

Certificate No:  
53899-2009-AQ-MCW-FINAS

Initial certification date:  
22 May 2009

Valid:  
22 January 2019 - 30 April 2021

This is to certify that the management system of

## **XEMA CO., LTD.**

bldg. 48, 9-th Parkovaya str., Moscow, Russian Federation, 105264  
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:  
**ISO 13485:2016**

This certificate is valid for the following scope:

**DESIGN, DEVELOPMENT, MANUFACTURING AND SALES OF KITS FOR IVD  
USE.**

Place and date:  
**Moscow, 22 January 2019**



For the issuing office:  
**DNV GL – Business Assurance  
Trekhpudny per. 9 build. 2, office 406,  
Moscow, Russian Federation**

*S. Groubine*

**Serguei Groubine**  
Management Representative

Certificate No: 53899-2009-AQ-MCW-FINAS  
Place and date: Moscow, 22 January 2019

## Appendix to Certificate

### XEMA CO., LTD.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
XEMA CO., LTD.	bldg. 48, 9-th Parkovaya str., Moscow, Russian Federation, 105264	DESIGN, DEVELOPMENT, MANUFACTURING AND SALES OF KITS FOR IVD USE.
XEMA Co., LTD ( production site)	Trubetskaya str., 2B, Balashikha, Moscow region, Russian Federation, 125000	DESIGN, DEVELOPMENT, MANUFACTURING AND SALES OF KITS FOR IVD USE.

