

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.