MANAGEMENT SYSTEM CERTIFICATE

Certificate No: 53899-2009-AQ-MCW-FINAS Initial certification date: 22 May 2009

Valid: 14 March 2018 - 28 February 2019

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 13485:2003**

This certificate is valid for the following scope: DESIGN, DEVELOPMENT, MANUFACTURING AND SALES OF KITS FOR IVD USE.

Place and date: Moscow, 14 March 2018





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

5. Groubine

Serguei Groubine Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info ACCREDITED UNIT: DNV GL BUSINESS ASSURANCE FINLAND OY AB, Keilasatama 5, 02150 Espoo, Finland. TEL:+358 10 292 4200. assurance.dnvgl.com Certificate No: 53899-2009-AQ-MCW-FINAS Place and date: Moscow, 14 March 2018

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.

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. This Certificate has been digitally signed. See Lack of fulliment of containing as set of an absolution of the set and the set