

Certificate

mdc medical device certification GmbH
certifies that

RPC "DIAGNOSTIC SYSTEMS", Ltd.
22, Yablonevaya Street
603093 Nizhny Novgorod
Russian Federation

with the locations listed in the attachment

for the scope

**development, manufacturing and distribution of
raw materials, reagents and in vitro diagnostic test kits for
infectious diseases, tumors, hormones and autoimmune diseases**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2018-05-09
Valid until	2021-04-17
Registration no.	D1199900032
Report no.	P17-01563-109260
Stuttgart	2018-05-09



Head of Certification Body



Attachment of the certificate

No. D1199900032

date 2018-05-09

Page 1 of 1

Location	Scope
RPC "DIAGNOSTIC SYSTEMS", Ltd., 195, Gorky Street, 603024 Nizhny Novgorod	distribution (marketing and administration)
RPC "DIAGNOSTIC SYSTEMS", Ltd., 22, Yablonevaya Street, 603093 Nizhny Novgorod	development, manufacturing and distribution of raw materials, reagents and in vitro diagnostic test kits for infectious diseases, tumors, hormones and autoimmune diseases
RPC "DIAGNOSTIC SYSTEMS", Ltd., 9 B, Barminskaya Street, 603022 Nizhny Novgorod	distribution (marketing, storage) and manufacturing of raw materials, reagents and in vitro diagnostic test kits for infectious diseases, tumors, hormones and autoimmune diseases
RPC "DIAGNOSTIC SYSTEMS", Ltd., 47, Kominterna Street, 603014 Nizhny Novgorod	distribution (administration)




Head of Certification Body