

# 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	2021-08-02
Valid until	2024-04-17
Registration no.	D1199900051
Report no.	P20-02055-212203
Stuttgart	2021-08-02

  
Head of Certification Body



Attachment of the certificate

No. D1199900051

date 2021-08-02

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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 603157 Nizhny Novgorod	distribution (administration)



  
Head of Certification Body