

# Certificate

**mdc medical device certification GmbH**  
certifies that

**ORGENTEC Diagnostika GmbH**  
**Carl-Zeiss-Straße 49 - 51**  
**55129 Mainz**  
**Germany**

with the locations listed in the attachment

for the scope

**design, development, manufacturing and distribution of  
in-vitro diagnostic test kits, reagents, controls and analyzers/instruments used  
in the diagnosis of autoimmune and infectious 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	2019-04-01
Valid until	2022-03-31
Registration no.	D1227900020
Report no.	P18-01487-133131
Stuttgart	2019-04-01



Head of Certification Body



**Attachment of the certificate**

**No. D1227900020**

date 2019-04-01

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Location	Scope
ORGENTEC Diagnostika GmbH Carl-Zeiss-Straße 49 – 51 55129 Mainz Germany	design, development, manufacturing and distribution of in-vitro diagnostic test kits, reagents, controls and analyzers/instruments used in the diagnosis of autoimmune and infectious diseases
ORGENTEC Austria GmbH Hausfeldstraße 90 A2232 Deutsch-Wagram Austria	distribution of in-vitro diagnostic test kits, reagents, controls and analyzers/instruments used in the diagnosis of autoimmune and infectious diseases
ORGENTEC Hungary Kft. Aradi Vértanúk utca 45 H2060 Bicske Hungary	distribution of in-vitro diagnostic test kits, reagents, controls and analyzers/instruments used in the diagnosis of autoimmune and infectious diseases



Head of Certification Body