

# 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 for autoimmune disease diagnostics, infectious diseases diagnostics, stool diagnostics and bone and mineral metabolism diagnostics**

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	2022-03-30
Valid until	2025-03-29
Registration no.	D1227900022
Report no.	P21-02052-223453
Stuttgart	2022-03-01

  
Head of Certification Body



**Attachment of the certificate**

**No. D1227900022**

date 2022-03-01

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<b>Location</b>	<b>Scope</b>
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 for autoimmune disease diagnostics, infectious diseases diagnostics, stool diagnostics and bone and mineral metabolism diagnostics
ORGENTEC Austria GmbH Hausfeldstraße 90 A2232 Deutsch-Wagram Austria	distribution of in-vitro diagnostic test kits, reagents, controls and analyzers/instruments used for autoimmune disease diagnostics, infectious diseases diagnostics, stool diagnostics and bone and mineral metabolism diagnostics
ORGENTEC Hungary Kft. Aradi Vértanúk utca 45 H2060 Bicske Hungary	distribution of in-vitro diagnostic test kits, reagents, controls and analyzers/instruments used for autoimmune disease diagnostics, infectious diseases diagnostics, stool diagnostics and bone and mineral metabolism diagnostics



  
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Head of Certification Body