

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