

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 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2016-08-16
Valid until	2019-08-15
Registration no.	D1227900017
Report no.	P16-00438-69739
Stuttgart	2016-08-02



Head of Certification Body



Attachment of the certificate

No. D1227900017

date 2016-08-02

Page 1 of 1

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	



Head of Certification Body