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

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
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Phone: +49-(0)711-253597-0
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Attachment of the certificate

No. D1227900017 date 2016-08-02

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 Biscske Hungary	

medical device certification mdc

Head of Certification Body

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