

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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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 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





Head of Certification Body