

Certificate

mdc medical device certification GmbH
certifies that

**Curetis GmbH
Max-Eyth-Straße 42
71088 Holzgerlingen
Germany**

with the locations listed in the attachment
for the scope

**Development, manufacturing and distribution of test kits, reagents,
devices and accessories for multiplex PCR based in-vitro diagnostic**

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.	D1413800004
Report no.	P18-01477-133037
Stuttgart	2019-03-11



Head of Certification Body



Attachment of the certificate

No. D141380004

date 2019-03-11

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Location	Scope
Curetis GmbH Max-Eyth-Straße 42, 71088 Holzgerlingen	Development, manufacturing and distribution of test kits, reagents, devices and accessories for multiplex PCR based in-vitro diagnostic
Curetis GmbH Robert-Bosch-Str. 4, 72411 Bodelshausen	Development, manufacturing and distribution of test kits, reagents, devices and accessories for multiplex PCR based in-vitro diagnostic



Head of Certification Body