

Certificate

mdc medical device certification GmbH
certifies that

gke-GmbH
Auf der Lind 10
65529 Waldems
Germany

for the scope

**design, production, distribution and service of
indicators and process challenge devices (PCDs) to monitor
cleaning and sterilization processes**

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	2018-12-14
Valid until	2020-12-18
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Head of Certification Body

