

Certificate

mdc medical device certification GmbH
certifies that

gke-GmbH
Auf der Lind 10 + 10A
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

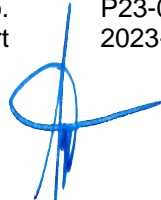
The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from	2023-12-19
Valid until	2026-12-18
Registration no.	D1196400004
Report no.	P23-01332-280689
Stuttgart	2023-12-19



Head of Certification Body

