

# Certificate

**mdc medical device certification GmbH**  
certifies that

**STRATEC SE**  
**Gewerbestraße 37**  
**75217 Birkenfeld**  
**Germany**

for the scope

**development, manufacturing and distribution of  
systems for process automation in diagnostics and biotechnology**

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	2018-12-12
Valid until	2021-05-16
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Head of Certification Body

