

# Certificate

**mdc medical device certification GmbH**  
certifies that

**STEFFENS BIOTECHNISCHE ANALYSEN GmbH**  
**Bötzingen Straße 29 B**  
**79111 Freiburg im Breisgau**  
**Germany**

for the scope

**Development and production of ELISA tests for human 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:2018 + A11:2021 - ISO 13485:2016

Valid from	2024-02-29
Valid until	2024-07-29
Registration no.	D1412300004
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Head of Certification Body

