

# Certificate

**mdc medical device certification GmbH**  
certifies that

**SERATEC**  
**Gesellschaft für Biotechnologie mbH**  
**Ernst-Ruhstrat-Straße 5**  
**37079 Göttingen**  
**Germany**

for the scope

**design, development, manufacture and sales of  
in-vitro diagnostic devices for determination of  
fertility, hormones, drug abuse, oncology and disease prevention**

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	2021-10-11
Valid until	2024-10-10
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Head of Certification Body

