

# 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, infectious diseases, oncology and disease prevention  
as well as of laboratory assays for the forensic application**

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 13485:2003 + AC:2007)

|                  |                        |
|------------------|------------------------|
| Valid from       | 2009-12-18             |
| Valid until      | 2014-12-18             |
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| Stuttgart        | 2009-12-18             |

  
Head of Certification Body

