

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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Head of Certification Body



mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: <http://www.mdc-ce.de>