

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 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2017-12-19
Valid until	2019-03-31
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Head of Certification Body

