

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	2018-10-11
Valid until	2021-10-10
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Head of Certification Body

