

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
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 9001

Quality management systems –
Requirements

(ISO 9001:2015)

Valid from	2021-10-11
Valid until	2024-10-10
Registration no.	D1063500034
Report no.	P21-01253-211764
Stuttgart	2021-09-16


Head of Certification Body



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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
Registration no.	D1063500035
Report no.	P21-01253-211768
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Head of Certification Body

