

## Certificate

We hereby certify the company

SERATEC Gesellschaft für Biotechnologie mbH Ernst-Ruhstrat-Straße 5 37079 Göttingen Germany

the introduction and application of a

## Quality management system according to EN ISO 13485

in the scope

design, development, manufacture and sales of in-vitro diagnostic devices for determination of fertility, hormones, drug abuse, oncology and disease prevention

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposes

Valid from 2024-10-16 Valid until 2027-10-10 Registration No. D1063500039 Report No. P24-01075-307346

Stuttgart, 2024-10-16

Certification Body

DAKKS

Deutsche
Akkreditierungsstelle
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