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

Stuttgart, 2024-10-16

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16002-06-00