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

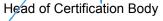
The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 9001

Quality management systems – Requirements

(ISO 9001:2015)

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







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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 Valid until Registration no. Report no. Stuttgart 2021-10-11 2024-10-10 D1063500035 P21-01253-211768 2021-09-16

Head of Certification Body





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