

Certificate

We hereby certify the company

STEFFENS BIOTECHNISCHE ANALYSEN GmbH
Bötzingen Straße 29 B
79111 Freiburg im Breisgau
Germany

the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

Development, manufacturing and distribution of ELISA tests for human diagnostics

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 2024-07-30
Valid until 2027-07-29

Registration No. D1412300005
Report No. P24-00514-296454

Stuttgart, 2024-07-24

A blue ink signature, likely of a representative of the Certification Body, is written in a cursive style.

Certification Body

