

Certificate

We hereby certify the company

PROGEN Biotechnik GmbH
Maaßstraße 30
69123 Heidelberg
Germany



the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

development, production and distribution of immunological reagents for IVD-applications and distribution of IVD for determination of disorders in coagulation.


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 2024-07-16
Valid until 2027-07-15

Registration No. D1266400006
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Stuttgart, 2024-07-09



Certification Body

