

Certificate

mdc medical device certification GmbH
certifies that

PROGEN

PROGEN Biotechnik GmbH
Maaßstraße 30
69123 Heidelberg
Germany

for the scope

**development, production and distribution of
in vitro diagnostic devices for infectious diseases,
disorders in lipid metabolism and coagulation, as well as for diagnostic devices for
research applications and immunological reagents for IVD-applications**

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

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Head of Certification Body

