

# Certificate

We hereby certify the company

**DiaMex GmbH**  
**Siemensstraße 38**  
**69123 Heidelberg**  
**Germany**

with the sites listed in the attachment the introduction and application of a

## **Quality management system according to EN ISO 13485**

in the scope

development, production and distribution of in vitro diagnostic medical devices for immunological and molecular biological assay methods

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 2024-12-28  
Valid until 2027-12-27

Registration No. D1329000046  
Report No. P24-00486-295966

Stuttgart, 2024-10-14



Certification Body



Sites included in the certification:

Location	Scope
DiaMex GmbH Hans-Bunte-Straße 6, 69123 Heidelberg Germany	development, production and distribution of in vitro diagnostic medical devices for immunological and molecular biological assay methods
DiaMex GmbH Siemensstraße 38, 69123 Heidelberg Germany	production and storage of in vitro diagnostic medical devices for immunological and molecular biological assay methods

Stuttgart, 2024-10-14



Certification Body