# Certificate

#### mdc medical device certification GmbH

certifies that

## Sifin diagnostics gmbh Berliner Allee 317-321 13088 Berlin Germany

for the scope

development, manufacturing and distribution of in vitro diagnostic medical devices for the product groups: blood grouping, bacteriological test reagents and culture media as well as manufacturing of raw materials for manufacturing of in vitro diagnostic medical devices

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 2021-10-23 2024-10-22 D1058700050 P21-00883-206453 2021-07-23

Head of Certification Body





mdc medical device certification GmbH Kriegerstraße 6 D-70191 Stuttgart, Germany Phone: +49-(0)711-253597-0 Fax: +49-(0)711-253597-10 Internet: http://www.mdc-ce.de