## Certificate

## mdc medical device certification GmbH

certifies that



K Line Europe GmbH Segro Park, Unit 203 K-J Bonner Straße 203-393 40589 Düsseldorf Germany

for the scope

Manufacture of custom-made dental devices (aligners)

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:2018 + A11:2021 - ISO 13485:2016

Valid from<br/>Valid until2023-06-26<br/>2025-05-23Registration no.<br/>Report no.<br/>BerlinD1502900003<br/>P23-00274-260155<br/>2023-06-26

Head of Certification Body





Internet: http://www.mdc-ce.de