

# Certificate

**mdc medical device certification GmbH**  
certifies that

**CARE diagnostica Produktions- und  
Vertriebsgesellschaft m.b.H.  
Roemerstraße 8  
2514 Traiskirchen  
Austria**

for the scope

**Development, manufacturing and distribution of immunochromatographic,  
enzymatic and clinical chemical rapid tests for in-vitro diagnosis as well as  
distribution of sterile swabs and blood lancets**

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	2023-06-27
Valid until	2025-03-31
Registration no.	D4002000019
Report no.	P23-00336-261123
Stuttgart	2023-06-27



Head of Certification Body

