

# Certificate

**mdc medical device certification GmbH**  
certifies that



**GFE Blut**

Gesellschaft zur Forschung, Entwicklung und Distribution  
von Diagnostika im Blutspendewesen mbH

**Altenhöferallee 3  
60438 Frankfurt am Main  
Germany**

with the locations listed in the attachment

for the scope

**development, manufacturing and distribution of  
molecular in vitro diagnostics for blood transfusion medicine**

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	2019-04-01
Valid until	2022-03-31
Registration no.	D1187700048
Report no.	P18-01043-126244
Stuttgart	2019-01-16

Head of Certification Body



**Attachment of the certificate**

**No. D1187700048**

date

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<b>Location</b>	<b>Scope</b>
Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH Altenhöferallee 5, 60438 Frankfurt am Main	administration, marketing and distribution of molecular in vitro diagnostics for blood transfusion medicine
Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH In der Schildwacht 11, 65933 Frankfurt am Main	storage and shipment of molecular in vitro diagnostics for blood transfusion medicine
Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH In der Schildwacht 13, 65933 Frankfurt am Main	manufacturing, storage and shipment of molecular in vitro diagnostics for blood transfusion medicine



A handwritten signature in blue ink, appearing to read "J. A.", is written over a horizontal line.

Head of Certification Body