# Certificate

**mdc medical device certification GmbH**
certifies that

**CE-Immundiagnostika GmbH**
**Karl-Landsteiner-Str. 6**
**69151 Neckargemünd**
**Germany**

for the scope

**design and development, manufacture and distribution of serological reagents for blood typing, in vitro diagnostics**

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 | 2021-05-10 |
| Valid until | 2024-05-09 |
| Registration no. | D1415300015 |
| Report no. | P20-01441-184458 |
| Stuttgart | 2021-02-10 |

Head of Certification Body

medical device certification mdc

Digitally signed by Talpiş Andrei
Date: 2021.07.15 08:02:32 EEST
Reason: MoldSign Signature
Location: Moldova

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

# EC Certificate

**mdc medical device certification GmbH**
Notified Body 0483
herewith certifies that

**CE-Immundiagnostika GmbH**
**Karl-Landsteiner-Str. 6**
**69151 Neckargemünd**
**Germany**

for the scope

**Reagents for blood typing:**
**AB0 system, Rhesus (C, c, D, E, e), Kell system, Duffy system,**
**Kidd system and determination of anti-irregular erythrocyte antibodies**

has introduced and applies a

## Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

## Annex IV – excluding Section 4 and 6 of the Council Directive 98/79/EC

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

| | |
|---|---|
| Valid from | 2021-05-10 |
| Valid until | 2024-05-26 |
| Registration no. | D1415300016 |
| Report no. | P20-01441-184463 |
| Stuttgart | 2021-02-10 |

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-247.10.05

# EC Certificate

**mdc medical device certification GmbH**
Notified Body 0483
herewith grants

**CE-Immundiagnostika GmbH**
**Karl-Landsteiner-Str. 6**
**69151 Neckargemünd**
**Germany**

for the scope

**Reagents for blood typing: AB0 system**
**(see attachment)**

the

## EC Design Examination Certificate

The examination of the design of the product by mdc has proven
that the design meets the requirements according to

## Annex IV – Section 4
## of the Council Directive 98/79/EC

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

This certificate is only valid in connection with a valid mdc certificate
according to Annex IV – excluding section 4 and 6 for the above mentioned products.

| | |
|---|---|
| Valid from | 2021-07-01 |
| Valid until | 2024-05-26 |
| Registration no. | D1415300017 |
| Report no. | P20-01451-184566 |
| Stuttgart | 2021-06-18 |

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-247.10.05

**Attachment of the certificate**

**No. D1415300017** Date 2021-06-18 

| Product category | Product | Class |
|---|---|---|
| Monoclonal antisera:<br>AB0-System | Anti-A, Klon A-11H5:<br>A-11H5-0010-01 / -05 / -10 / -20 / -50<br>Anti-A, Klon BIRMA-1:<br>A-BIRMA-0010-01 / -05 / -10 / -20 / -50<br>Anti-B, Klon B-6F9:<br>B-6F9-0010-01 / -05 / -10 / -20 / -50<br>Anti-B, Klon LB-2:<br>B-LB2-0010-01 / -05 / -10 / -20 / -50<br>Anti-AB, Klon A-5E10-B-2D7:<br>AB-5E10-0010-01 / -05 / -10 / -20 / -50 | List A,<br>Annex II |

Head of Certification Body

# EC Certificate

**mdc medical device certification GmbH**
Notified Body 0483
herewith grants

**CE-Immundiagnostika GmbH**
**Karl-Landsteiner-Str. 6**
**69151 Neckargemünd**
**Germany**

for the scope

**Reagents for blood typing: Kell**
**(see attachment)**

the

## EC Design Examination Certificate

The examination of the design of the product by mdc has proven
that the design meets the requirements according to

## Annex IV – Section 4
## of the Council Directive 98/79/EC

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

This certificate is only valid in connection with a valid mdc certificate
according to Annex IV – excluding section 4 and 6 for the above mentioned products.

| | |
|---|---|
| Valid from | 2021-07-01 |
| Valid until | 2024-05-26 |
| Registration no. | D1415300018 |
| Report no. | P20-01446-184512 |
| Stuttgart | 2021-06-18 |

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-247.10.05

**Attachment of the certificate**

**No. D1415300018** Date 2021-06-18 Page 1 of 1

| Product category | Product | Class |
|---|---|---|
| Monoclonal and polyclonal antisera: Kell-System | Anti-Kell, Klon MS56:<br>Kel-MS56-0005-01 / -05 / -10 / -20 / -50,<br>Kel-MS56-0010-01 / -05 / -10 / -20 / -50<br>Anti-Kell, Klon AEK4:<br>Kel-AEK4-0005-01 / -05 / -10 / -20 / -50,<br>Kel-AEK4-0010-01 / -05 / -10 / -20 / -50<br>Anti-Kell coombsreactive:<br>Kel-coom-0005-01 / -05 / -10 / -20 / -50,<br>Kel-coom-0010-01 / -05 / -10 / -20 / -50 | List A, Annex II |

Head of Certification Body

medical device certification mdc