

bsi.



# Certificate

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Benannt durch / Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
ZLG-BS-249.10.03

First Issue Date:  
21 February 2012.

Based on periodical surveillance  
this certificate is valid until  
20 February 2021.

## EC-Certificate

(full quality assurance system)  
according to Annex IV Section 3 of the Directive 98/79/EC  
on in vitro diagnostic medical devices

It is herewith confirmed by

### BSI Group Deutschland GmbH

Eastgate, Hanauer Landstrasse 115  
60314 Frankfurt am Main  
Germany

in its function as Notified Body (0535), that the manufacturer:

### CE-Immundiagnostika GmbH

Am Seerain 13  
74927 Eschelbronn, Germany

concerning the medical devices

### Products of blood typing

(products/variants specified in appendix)

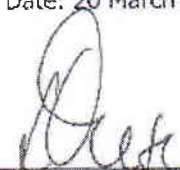
fulfills the requirements according to Annex IV, Section 3 of  
the Directive 98/79/EC of the European Parliament and the  
Council of 27 October 1998 on in vitro diagnostic medical  
devices. The manufacturer has established a quality  
assurance system for the design, production and final  
inspection of specified devices.

For marketing of Annex II list A products an Annex IV  
Section 4 certificate is mandatory.

The appendix is part of this certificate and contains 1 page.

Report No.: SMO7685167  
Certificate No: CE574256

Current Issue Date: 20 March 2013

  
Certification Body



# Certificate

**mdc medical device certification GmbH**  
certifies that

**CE-Immundiagnostika GmbH**  
**Am Seerain 13**  
**74927 Eschelbronn**  
**Germany**

for the scope

**design and development, manufacture and distribution of  
serological reagents for blood typing, in vitro diagnostic 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 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2016-07-01
Valid until	2019-06-30
Registration no.	D1415300001
Report no.	P16-00412-69438
Stuttgart	2016-07-01



Head of Certification Body



# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**CE-Immundiagnostika GmbH  
Am Seerain 13  
74927 Eschelbronn  
Germany**

for the scope

**Reagents for blood typing:  
AB0 system, Rhesus (C, c, D, E, e), Kell system,  
Duffy system, Kidd system, anti-irregulate erythrocytes**

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	2016-07-01
Valid until	2021-06-30
Registration no.	D1415300002
Report no.	P16-00412-69442
Stuttgart	2016-07-01



Head of Certification Body



# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith grants

**CE-Immundiagnostika GmbH  
Am Seerain 13  
74927 Eschelbronn  
Germany**

for the scope

**Reagents for blood typing:  
ABO system, Rhesus, 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	2016-07-01
Valid until	2021-06-30
Registration no.	D1415300004
Report no.	P16-00413-76820
Stuttgart	2016-06-30



Head of Certification Body



**Attachment of the certificate**

**No. D1415300004**

Date 2016-06-30

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Product category	Product	Class
monoclonal and polyclonal antisera: Anti-A, Anti-B, Anti-AB, Anti-C, Anti-c, Anti-E, Anti-e, Anti-Kell	Anti-A A-11H5, Anti-A BIRMA-1, Anti-B B-6F9, Anti-B LB-2, Anti-AB A-5E10-B-2D7 Anti-C MS24, Anti-C MS273 , Anti-c MS33, Anti-c MS35, Anti-c incomplete, Anti-E MS80/MS258, Anti-E MS12/MS260, Anti-E incomplete, Anti-e MS16/MS21/MS63, Anti-e MS62/MS69, Anti-e incomplete Anti-Kell AEK4	List A, Annex II



Head of Certification Body

