Digitally signed by Talpiş Andrei
Date: 2019.01.24 10:05:46 EET
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Location: Moldova

Certificate

...making excellence a habit.™

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

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

First Issue Date:
21 February 2012.

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

Current Issue Date: 20 March 2013

Certification and Testing · BSI Group Deutschland GmbH ·

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

medical device certification mdc

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

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany

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

medical device certification mdc

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

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany

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:
AB0 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

medical device certification mdc

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

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany

Attachment of the certificate

No. D1415300004 Date 2016-06-30 Page 1 of 1

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

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany