

# EC Certificate

mdc medical device certification GmbH

Notified Body 0483  
herewith certifies that



**Human Gesellschaft für Biochemica und Diagnostica mbH**  
**Max-Planck-Ring 21**  
**65205 Wiesbaden**  
**Germany**

for the scope

Testkits for the determination of HIV, HBV, HCV, tumor marker PSA,  
rubella, toxoplasmosis, chlamydiae, CMV (ELISA, PCR);

blood grouping test sera: ABO-system, Rhesus (D);

products for the determination of blood glucose as selftests:  
HumaSens (blood glucose meter, test strips, control solution)  
(see attachment)

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	2015-10-26
Valid until	2019-03-11
Registration no.	D1030000043
Report no.	P14-01722-32384
Stuttgart	2015-10-26

  
Head of Certification Body



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Benannt durch/Designated by  
Zentralstelle der Länder für  
Gesundheitsschutz bei  
Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-247.10.05

**Attachment of the certificate**

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Product category	Product	Class
Blood grouping test sera: ABO-system	HumaType Anti-A Blood grouping test sera Anti-A, monoclonal murine IgM cell line 11H5 71012	List A, Annex II
	HumaType Anti-B Blood grouping test sera Anti-B, monoclonal murine IgM cell line 6F9 71022	List A, Annex II
	HumaType Anti-A,B Blood grouping test sera Anti-AB, monoclonal murine IgM cell line 5E10/2D7 71032	List A, Annex II
Blood grouping test sera: Rhesus (D)	HumaType Anti-D IgM Blood grouping test sera Anti-D, monoclonal human IgM cell line RUM-1 71042	List A, Annex II
	HumaType Anti-D IgM/IgG Blood grouping test sera Anti-D, monoclonal murine IgM/IgG cell line TH-28/MS-26 71052	List A, Annex II
Products for the determination of blood glucose as selftests: HumaSens (blood glucose meter, test strips, control solution)	HumaSens Blood glucose meter, starter pack with glucose test strips and control solution for selftesting 17540	List B, Annex II
	HumaSens (without lancing device and lancets) Blood glucose meter, starter pack with glucose test strips and control solution for selftesting 17540-1	List B, Annex II
	HumaSens Blood glucose meter, starter pack with glucose test strips and control solution for selftesting 17540/E2	List B, Annex II
	HumaSens/HumaSens Plus Glucose Test Strips Glucose test strips for use with HumaSens glucose meter and HumaSens plus multi-parameter-system for the determination of glucose levels in capillary whole blood 17542/25	List B, Annex II



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Product category	Product	Class
Products for the determination of blood glucose as selftests: HumaSens (blood glucose meter, test strips, control solution)	HumaSens/HumaSens Plus Glucose Test Strips Glucose test strips for use with HumaSens glucose meter and HumaSens plus multi-parameter-system for the determination of glucose levels in capillary whole blood 17542/25/E2	List B, Annex II
	HumaSens/HumaSens Plus Glucose Control solution normal Glucose control solution for quality control of HumaSens and HumaSens plus meters and glucose test strips 17545	List B, Annex II
	HumaSens/HumaSens Plus Glucose Control solution normal Glucose control solution for quality control of HumaSens and HumaSens plus meters and glucose test strips 17545/E2	List B, Annex II
Testkits for the determination of chlamydiae	Hexagon Chlamydia Immunochemical rapid test for the direct detection of chlamydia antigen in extracts of patient samples (endocervical or urethral smears) 58012	List B, Annex II
	Hexagon Chlamydia Collect Immunochemical rapid test for the direct detection of chlamydia antigen in extracts of patient samples (endocervical or urethral smears) 58912	List B, Annex II
	Chlamydia Trachomatis IgG ELISA ELISA for the quantitative determination of IgG antibodies against Chlamydia trachomatis in human serum and plasma 51228	List B, Annex II
	Chlamydia Trachomatis IgA ELISA ELISA for the determination of IgA antibodies against Chlamydia trachomatis in human serum and plasma 51328	List B, Annex II



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Product category	Product	Class
Testkits for the determination of CMV	CMV IgM ELISA ELISA test for the determination of anti-cytomegalovirus IgM antibodies in human serum 51103	List B, Annex II
	CMV IgG ELISA ELISA test for the determination of anti-cytomegalovirus IgG antibodies in human serum 51203	List B, Annex II
	CMV Real-Time PCR Kit Real-Time PCR test for the quantitative detection of Cytomegalovirus DNA in human serum or plasma 87030	List B, Annex II
Testkits for the determination of HBV	HBsAg ELISA HBsAg ELISA test for the determination of HBs antigen 51048	List A, Annex II
	HBV Real-Time PCR Kit Real-Time PCR test for the quantitative detection of Hepatitis B Virus DNA in human serum or plasma 87120	List A, Annex II
Testkits for the determination of HCV	anti-HCV ELISA Immunoassay for the qualitative detection of antibodies against Hepatitis C virus in human serum or plasma samples (3rd generation) 51275, 51250	List A, Annex II
	HCV Real-Time PCR Kit Real-Time PCR test for the quantitative detection of Hepatitis C Virus RNA in human serum or plasma 87110	List A, Annex II



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Testkits for the determination of HIV	Hexagon HIV Immunochromatographic rapid test for the detection of antibodies against HIV 1 and 2 57002P, 57004P	List A, Annex II
	anti-HIV 1/2 ELISA ELISA for the determination of antibodies against HIV-1 and HIV-2 in human serum and plasma 51205C	List A, Annex II
	HIV Ag/Ab ELISA ELISA for the determination of antibodies against HIV-1 and HIV-2, HIV-1 subtype O and p24 antigen in human serum and plasma 51215	List A, Annex II
	HIV-1 Real-Time PCR Kit Real-Time PCR test for the quantitative detection of HIV-1 RNA in human serum or plasma 87100	List A, Annex II
Testkits for the determination of rubella	Rubella IgM µ-capture ELISA for the determination of IgM antibodies against rubella virus in human serum and plasma 51108	List B, Annex II
	Rubella IgG ELISA test for the determination of anti-rubella virus IgG antibodies in human serum 51208	List B, Annex II
Testkits for the determination of toxoplasmosis	Toxo IgM µ-capture ELISA ELISA for the determination of IgM antibodies against Toxoplasma gondii in human serum and plasma 51119	List B, Annex II
	Toxo IgG ELISA ELISA test for the determination of anti-Toxoplasma gondii IgG antibodies in human serum 51209	List B, Annex II



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Product category	Product	Class
Testkits for the determination of tumor marker PSA	Hexagon PSA Immunochromatographic rapid test for the detection of prostate specific antigen (PSA) in serum, plasma and whole blood 28032	List B, Annex II
	PSA ELISA ELISA test for the determination of total prostate specific antigen in human serum 52030	List B, Annex II
	fPSA ELISA ELISA test for the quantitative determination of free prostate specific antigen in human serum 52035	List B, Annex II

unauthorized



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