

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,
rubella, toxoplasmosis, chlamydiae, CMV, tumor marker PSA;
products for the determination of blood glucose as selftests
(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	2022-03-12
Valid until	2025-05-26
Registration no.	D1030000085
Report no.	P21-01793-219735
Stuttgart	2022-03-10




Head of Certification Body



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

Attachment of the certificate

No. D1030000085

Date 2022-03-10

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Product category	Product	Class
Testkits for the determination of HIV	Hexagon HIV Immunochromatographic rapid test for the detection of antibodies against HIV 1 and 2 (57002P, 57004P) 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
Testkits for the determination of HBV	HBsAg ultra sens, ELISA Test for the determination of HBs-Antigen (51050)	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)	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) 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) 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 CMV	CMV IgM ELISA ELISA test for the determination of anti-cytomegalovirus IgM antibodies in human serum (51103) CMV IgG ELISA ELISA test for the determination of anti-cytomegalovirus IgG antibodies in human serum (51203)	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) 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
Testkits for the determination of tumor marker PSA	Hexagon PSA Immunochemical rapid test for detection of prostata-specific antigen (PSA) in serum, plasma and whole blood (28032) PSA ELISA ELISA test for the determination of total prostata specific antigen in human serum (52030)	List B, Annex II





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Product category	Product	Class
Testkits for the determination of tumor marker PSA	fPSA ELISA ELISA test for the quantitative determination of free prostata specific antigen in human serum (52035) PSA HumaCLIA SR Chemiluminescence Immunoassay (CLIA) for the quantitative determination of total Prostate Specific Antigen in human serum and plasma (83130) fPSA HumaCLIA SR Chemiluminescence Immunoassay (CLIA) for the quantitative determination of free Prostate Specific Antigen in human serum and plasma (83125)	List B, Annex II
Products for the determination of blood glucose as selftests: HumaSens (blood glucose meter, test strips, control solution)	HumaSens2.0 Starter Pack (17560) Glucose Test Strips Blue HumaSens2.0/HumaSens2.0 Plus/ HumaSens/HumaSens Plus (2x25) (17562) Glucose Control HumaSens/HumaSens Plus/HumaSens2.0/ HumaSens2.0 Plus (BLUE GLU strip) (17562/10)	List B, Annex II




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