

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

VEDALAB
Rue de l'Expansion,
ZAT du Londeau - Cerisé - B.P. 181
61006 Alençon cedex
France

for the scope

Chlamydia trachomatis immunochromatographic rapid test;
immunochromatographic tests for PSA qualitative detection for self-testing use;
immunochromatographic tests for PSA qualitative, quantitative and
semi-quantitative detection with readers including positive and negative controls;
immunochromatographic rapid tests for self-testing use
(see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

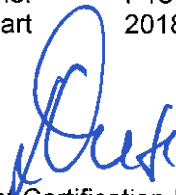
The mdc audit has proven that this quality system
meets all requirements according to

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	2018-07-31
Valid until	2020-11-02
Registration no.	D1086900060
Report no.	P18-00189-124939
Stuttgart	2018-07-02



Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Arzneimittel- und
Medizinprodukte
www.zlg.de
ZLG-BS-247.10.05

Attachment of the certificate

No. D1086900060

Date 2018-07-02

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Product category	Product	Class
Chlamydia trachomatis immunochromatographic rapid test	CHLAMY-CHECK-1, REF 1001, 1002, 1003, 1071, 1072, 1073, 1071-4, 1071-MS-4	List B, Annex II
FSH menopause rapid test for self-testing	FSH-CHECK-1, REF 11037, 11036 Klimakterie FSH-CHECK-1, REF 11037BI FSH-CHECK-1 cassette, REF 11006C, 11076, 11076-4, 11076-MS-4 FSH-CHECK-1 Midstream MENO-CHECK®, REF 11066, 11066-11, 11066-12, 11084, 11066AO, 11084AV SloNO MENOPAUSA, REF 11066J	Self-testing not Annex II
hCG pregnancy test for self-testing device	BABYCHECK-1®, REF 3006A, 3006B, 3006C, 3076, 3076-4, 3076-MS-4 MONO-TEST, REF 3003 Evidence-10, REF 3066-10, 3061-12-10, 3061-11-10 EVIDENCE, REF 3060, 3066, 3061-11, 3061-12 dr.bosshammer-hCG, REF 3061-12-10B JUMBO zwangerschapstest, REF 3061-11-10AY leidapharm zwangerschapstest, REF 3061-11-10AZ Sanelco zwangerschapstest, REF 3061-11-10BA APOTEX zwangerschapstest, REF 3061-11-10BB Babycheck Plus-10, REF 3084-10 Babycheck Plus®, REF 3084 BABYCHECK-1, REF 3060 SloNO GRAVIDANZA 1 TEST, REF 3066J SloNO GRAVIDANZA 2 TESTS, REF 3066J-2	Self-testing not Annex II
hCG strip pregnancy test for self-testing	hCG STRIP, REF 3037B, 3037C Graviditet hCG STRIP, REF 3037BI Babycheck® strip, REF 3037B-1, 3037C-1, 3037L SloNO GRAVIDANZA 1 TEST STRISCIA, REF 3037J Baby CHECK® Strip Mini, REF 3033 Baby CHECK® QUICK, REF 3033-1 hCG STRIP-10, REF 3037B-10, 3037C-10 BB TEST® 10IU/L, REF 3039B-10 Graviditet Evidence, REF 3066BI	Self-testing not Annex II





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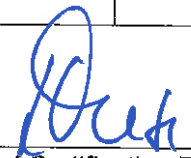
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Product category	Product	Class
Immunochemical test for detection of blood in faeces for self-testing	POLY-CHECK [®] , REF 4084, 4084L, 4084AR, 4084AV, 4084AO POLY-CHECK Darmkrebsvorsorgetest, REF 4084B, 4084AT FEC.O.TEST [®] , REF 4084BC Darmkrebsvorsorgetest Heumann, REF 4084I SloNO COLON RETTO, REF 4084J YesNo Självtest Dolt Bold, REF 4084AL	Self-testing not Annex II
Immunochemical tests for free PSA quantitative and semi-quantitative detection with rapid tests readers	Free PSA-CHECK-1, REF F8091, F8091-10T	List B, Annex II
Immunochemical tests for PSA qualitative detection	PSA-CHECK-1 qualitative test, REF 8051A, 8051B, 8051C, 8081 PSA-CHECK-1 OK, qualitative test, REF 8087, 8081B	List B, Annex II
Immunochemical tests for PSA qualitative detection for self-testing use	PROSTA-CHECK [®] REF 8084, 8084D, 8084L, 8084AO, 8084AR, 8084AV; 8084BE, 8184 PSA-CHECK-1 HOMETEST, REF 8084AW, 8084AX, 8084B, 8084AT PROSTATA SCHNELLTEST, REF 8084T PSA Test, REF 8084C ApoLife [®] PROSTATA-PSA-TEST, REF 8084BD SloNO PROSTATA, REF 8084J YesNo Kotitesti Prostata, REF 8084AN YesNo Självtest Prostata, REF 8084AL Alere [™] Prostate Home Test, REF 8084AE PROST.A.TEST, REF 8084BC Prostate PSA Test, MV88006-PSA	List B, Annex II
Immunochemical tests for PSA quantitative and semi-quantitative detection with rapid tests readers including positive and negative controls	PSA-CHECK-1, quantitative and semi-quantitative detection with rapid tests readers including positive and negative controls, REF 8091, 8091-S PSA medium positive control, REF V040 PSA strong positive control, REF V041 PSA negative control, REF V045	List B, Annex II





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LH ovulation rapid test for self-testing	L-CHECK-1, REF 5037, 5037L Agglossning L-CHECK-1, REF 5037BI SloNO OVULAZIONE STRISCIA, REF 5037J L-CHECK-1 Cassette, REF 5006A, 5006B, 5006C, 5076, 5076-4, 5076-MS-4 L-CHECK-1 Midstream, REF 5066, 5066-11, 5084, 5084AV Babycheck Plus® ovulation test, REF 5060 SloNO OVULAZIONE STICK, REF 5066J	Self-testing not Annex II
Self-testing device for determination of human chorionic gonadotropin (hCG) level above 1000 IU/mL in urine to check the outcome of termination of pregnancy	Check4®-hCG (hl), REF 3066-1000AG, 3067-1000AG / checkToP®, REF 3066-1000AI, 3067-1000AI	Self-testing not Annex II
Self-testing rapid test for anti-borrelia IgM antibody detection in whole blood	TIK'ALERT®, REF 70084, 70084B, 70084AO, 70084F, 70084AV, 70184 Alere™ Lyme Home Test, REF 70084AE Borreliosis Test (Lyme), REF MV88488-BOR	Self-testing not Annex II
Self-testing rapid test for detection of antibodies against helicobacter pylori bacteria in whole blood	PYLORI-Screen® REF 17084, 17084B, 17084AO, 17084AR, 17084AV, 17184 Alere™ H-pylori Home Test, REF 17084AE SloNO HELICOBACTER PYLORI, REF 17084J Helicobacter Test, REF MV88150-HP	Self-testing not Annex II
Self-testing rapid test for detection of hypothyroidism in whole blood	THYRO-Check® REF 21084, 21084AO, 21084AR, 21084AV Alere™ Thyroide Home Test, REF 21084AE	Self-testing not Annex II
Self-testing rapid test for detection of iron deficiency in whole blood	FERRI-Check®, REF 25084, 25084AO, 25084AV, 25184, KST25084EP ApoLife® EISEN-FER-TEST, REF 25084BD Alere™ Fer Home Test, REF 25084AE Anemia Test, REF MV88129-FER	Self-testing not Annex II




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Product category	Product	Class
Self-testing rapid test for IgE detection in whole blood	ALLERGY-Check [®] , REF 18084, 18084AO, 18084AV, 18084BE, 18184 Alere [™] Allergie Home Test, REF 18084AE Allergy Test, REF MV88105-ALG	Self-testing not Annex II
Self-testing rapid test for the assessment of tetanus protection	TETANOSTOP [®] , REF 92084, 92084AO, 92084AV Alere [™] Tétanos Home Test, REF 92084AE	Self-testing not Annex II
Self-testing rapid test for the detection of antibodies against Syphilis (Treponema pallidum) in whole blood	Syph-Check-1 [®] , REF 26084, 26184, 26084AV Syphilis Test, REF MV87979-SYP VENERIS Test Rapid Sifilis, REF 26084BG	Self-testing not Annex II
Self-testing rapid test for the detection of C-reactive protein (CRP) in whole blood	CRP-Screen [®] , REF 34084, 34184, 34084AO Inflammation CRP Test, REF MV88020-CRP	Self-testing not Annex II
Self-testing rapid test for the detection of gluten intolerance	GLUTEN'ALARM [®] , REF 150084	Self-testing not Annex II
Self-testing whole blood rapid test for assessment of liver physiological status	LIVER-Screen [®] , REF 999984W-3L, 999984W-3L-AO	Self-testing not Annex II
Strip immunochromatographic rapid test for self-testing of albumin in urine	M-ALBU-CHECK-1 Strip, REF 27037, 27037L, 27037AO, 27037AV, 27037BE SiONO ALBUMINA TEST, REF 27037J Alere [™] Albumine Home Test, REF 27037AE	Self-testing not Annex II





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