

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**Prima Lab SA
Via Antonio Monti 7
6828 Balerna
Switzerland**

for the scope

**testing devices for the detection of prostate specific antigen PSA and
immunochromatographic rapid self testing devices
(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	2019-04-17
Valid until	2021-01-18
Registration no.	D1408400018
Report no.	P18-01432-132182
Stuttgart	2019-04-17



Head of Certification Body



Attachment of the certificate

No. D1408400018

Date 2019-04-17

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Product category	Product	Class
testing devices for the detection of prostate specific antigen PSA	Prostate PSA Test, My Test Prostate, Profar Test PSA, MyTest Prostaat (REF 100080, 300080, 380080, 800080, 801080)	List B, Annex II
immunochromatographic rapid self testing devices	<p>Tetanus Test, My Test Tétanos (REF 100092, 300092), Rapid self testing device for the assessment of tetanus protection</p> <p>Bowel FOB Test, My Test Colorectal, Profar Test Colon Retto (REF 100040, 300040, 800040, 801040, 380040), Rapid self testing device for the detection of blood in faeces</p> <p>Iron FER Test, My Test Fer (REF 100025, 300025), Rapid self testing device for the detection of iron deficiency in whole blood</p> <p>Ferritin Test, MyTest Jern, MyTest - Ferro, MyTest Eisenmangel, FerriCheck (REF 380025, 800025, 802025), rapid self-test for the detection of Ferritin level in blood</p> <p>Helicobacter pylori Test, My Test H.pylori-Ulcère, MyTest Magen-Vorsorge (H.pylori) (REF 100017, 300017, 800017, 380017), Rapid self testing device for the detection of antibodies against Helicobacter Pylori</p> <p>Thyroid TSH Test, My Test Thyroïde (REF 100021, 300021), Rapid self testing device for the detection of hypothyroidism</p> <p>Allergy IgE Test, My Test Allergie, MyTest Allergi, MyTest Allergia (REF 100018, 300018, 800018, 380018), Rapid self testing device for the detection of total IgE</p> <p>Kidneys Albumin Test, My Test Albumine (REF 100027, 300027, 800027, 380027), Rapid self testing device for urinary albumin</p> <p>Menopause FSH Test, My Test Ménopause, MyTest Menopause, Estromineral MyTest - Menopausa (REF 100011, 300011, 800011, 380011), PRODECO PHARMA MY TEST - Menopause FSH Test (REF DW01.0030), Rapid self testing device for the detection of follicle stimulating hormone FSH</p>	Self testing not Annex II



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immunochemical rapid self testing devices	<p>Ovulation LH Test, Test di ovulazione Securtest® (REF 100050, 800050, 801050), Rapid self testing device for the detection of luteinizing hormone LH</p> <p>Pregnancy hCG Test (REF 100030, 800030), GALECOLINE Pregnancy Test Easy (REF 500031-1, 500031-2), AMAVITA Schwangerschafts Schnelltest (REF 500032-1, 500032-2), SUNSTORE MED Schwangerschaftstest (REF 500033-1, 500033-2), Coop Vitality Schwangerschaftstest (REF 500035-1, 500035-2), G-PHARMA Schwangerschaftstest (REF 500036-1), Rapid self testing device for the detection of human chorionic gonadotropin hCG</p> <p>Urinary Tract Infections Test, My Test Infection Urinaire, MyTest Harnwegsinfekt, My Test Urineweg-infectie (REF 100058, 300058)</p> <p>Borrelia Tick Test, My Test Lyme (REF 100070, 300070)</p> <p>Cholesterol Test, My Test Cholestérol, COLLIPID, MyTest Cholesterol, Armolipid MyTest - Colesterolo, MyTest Cholesterin (REF 100049, 300049, 400049)</p> <p>C-Reactive Protein Test, My Test C-Reactive Protein (REF 100034, 300034)</p> <p>AMNIOCHECK, AMNIOSENSE, SAUGELLA AmnioCheck, AMNIOS, AMNIODETECT, AL-SENSE, Barza Amniotest (REF 100088-5, 100088-10, 100088-30, 300088, 600088, 700088, 900088-2, 900088-50, 710088)</p> <p>Celiac Test, My Test Maladie coeliaque, MyTest Glutenintoleranz, MyTest - Celiachia (REF 100077, 300077)</p> <p>Vaginal pH Test (REF 100013-3, 100013-5), self-test for the semi-quantitative determination of pH in female vaginal swab specimens</p> <p>Sperm Test (REF 100082), self-test for in vitro qualitative estimation of sperm concentration in human semen</p> <p>ExAller® Dust Mite Allergy Self-Test (REF 800015), self-test for the detection of House Dust-mite specific IgE in whole blood</p>	Self testing not Annex II



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