

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that



**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	2017-11-20
Valid until	2021-01-18
Registration no.	D1408400012
Report no.	P17-01532-108872
Stuttgart	2017-11-20

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. D1408400012

Date 2017-11-20

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Product category	Product	Class
testing devices for the detection of prostate specific antigen PSA	Prostate PSA Test, My Test Prostate (REF 100080, 300080)	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 (REF 100040, 300040), 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>Helicobacter Pylori Test, My Test H.pylori-Ulcère (REF 100017, 300017), 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 (REF 100018, 300018), Rapid self testing device for the detection of total IgE</p> <p>Kidneys Albumin Test, My Test Albumine (REF 100027, 300027), Rapid self testing device for urinary albumin</p> <p>Menopause FSH Test, My Test Ménopause (REF 100011, 300011), PRODECO PHARMA MY TEST - Menopause FSH Test (REF DW01.0030), Rapid self testing device for the detection of follicle stimulating hormone FSH</p> <p>Ovulation LH Test (REF 100050), Rapid self testing device for the detection of luteinizing hormone LH</p>	Self testing not Annex II



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Product category	Product	Class
immunochematographic rapid self testing devices	Pregnancy hCG Test (REF 100030), 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 Urinary Tract Infections Test, My Test Infection Urinaire (REF 100058, 300058) Borrelia Tick Test, My Test Lyme (REF 100070, 300070) Cholesterol Test, My Test Cholestérol, COLLIPID (REF 100049, 300049, 400049) C-Reactive Protein Test, My Test C-Reactive Protein (REF 100034, 300034) AMNIOCHECK, AMNIOSENSE, My Test AMNIO, AMNIOS, AMNIODETECT (REF 100088-5, 100088-10, 300088, 600088, 700088) Celiac Test, My Test Maladie coeliaque (REF 100077, 300077)	Self testing not Annex II



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