

# 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	2016-01-19
Valid until	2021-01-18
Registration no.	D1408400003
Report no.	P15-01213-52921
Stuttgart	2016-01-19

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. D1408400003**

Date 2016-01-19

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Product category	Product	Class
testing devices for the detection of prostate specific antigen PSA	Prima Home Test: Prostate PSA Test (REF 100080)	List B, Annex II
immuno-chromatographic rapid self testing devices	Tetanus Test (REF 100092), Rapid self testing device for the assessment of tetanus protection Bowel FOB Test (REF 100040), Rapid self testing device for the detection of blood in faeces Ferritin FER Test (REF 100025), Rapid self testing device for the detection of iron deficiency in whole blood Helicobacter Pylori Test (REF 100017), Rapid self testing device for the detection of antibodies against Helicobacter Pylori Thyroid TSH Test (REF 100021), Rapid self testing device for the detection of hypothyroidism Allergy IgE Test (REF 100018), Rapid self testing device for the detection of total IgE Kidneys Albumin Test (REF 100027), Rapid self testing device for urinary albumin Menopause FSH Test (REF 100011), Rapid self testing device for the detection of follicle stimulating hormone FSH Ovulation LH Test (REF 100050), Rapid self testing device for the detection of luteinizing hormone LH Pregnancy hCG Test (REF 100030), Rapid self testing device for the detection of human chorionic gonadotropin hCG Urinary Tract Infections Test (REF 100058) Cholesterol Test (REF 100049) Borrelia Tick Test (REF 100070)	Self testing



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