

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**CARE diagnostica Produktions- und  
Vertriebsgesellschaft m.b.H.**

**Roemerstraße 8  
2513 Moellersdorf  
Austria**

for the scope

**tests for detection of Chlamydia trachomatis (for professional use and for self-testing)  
tests for blood glucose for self-testing  
tests for self-testing (hCG, hLH, FSH, vaginal pH, fecal occult blood, Cholesterol,  
LDL Cholesterol, urinary infection, antibodies against H. Pylori)  
(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	2016-11-04
Valid until	2020-05-19
Registration no.	D4002000001
Report no.	P16-01469-82933
Stuttgart	2016-11-04



Head of Certification Body



**Attachment of the certificate**

**No. D400200001**

Date 2016-11-04

Page 1 of 3

Product category	Product	Class
Tests for detection of Chlamydia trachomatis (for professional use and for self-testing)	chlamyCARE-C (rapid immunochromatographic assay for qualitative detection of Chlamydia trachomatis in endocervical or endourethral swab specimen) viola® Chlamydia Test (for qualitative detection of Chlamydia trachomatis in vaginal swab specimen for self-testing) ABBLO® PHARMA Chlamydia test (for qualitative detection of Chlamydia trachomatis in vaginal swab specimen for self-testing) Veroval® SELF-TEST Chlamydia (for qualitative detection of Chlamydia trachomatis in vaginal swab specimen for self-testing) mediola Chlamydia Rapid Test (for qualitative detection of Chlamydia trachomatis in vaginal swab specimen for self-testing) Veneris® Test for detection of infection with Chlamydia trachomatis cyclotest® Chlamydia Rapid Test (for qualitative detection of Chlamydia trachomatis in vaginal swab specimen for self-testing)	List B, Annex II
Tests for determination of blood glucose in whole blood (for self-testing)	myCARE® Blood Glucose Health Care Test YesNo Self-test Blood Glucose Boots PHARMACEUTICALS Blood Glucose Home Test Kit	List B, Annex II
Tests for detection of antibodies against H. Pylori in whole blood (for self-testing)	myCARE® Stomach Ulcer Health Care Test myCARE® Helicobacter Health Care Test ApoLife® Helicobacter pylori-Test	Self testing, not Annex II
Tests for detection of fecal occult blood (for self-testing)	myCARE® Colon Polyps/Bowel Health Care Test myCARE® Colon Health Care Test myCARE® Blut im Stuhl-Test zur Darmkrebsvorsorge	Self testing, not Annex II
Tests for detection of FSH in urine (for self-testing)	viola® Menopause Test (for detection of FSH (25 IU/l) in urine) Ferlidona Menopause Test (for detection of FSH (25 IU/l) in urine) YesNo Self-test Menopause Test (for detection of FSH (25 IU/l) in urine)	Self testing, not Annex II



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Date 2016-11-04

Page 2 of 3

Product category	Product	Class
Tests for detection of hCG in urine (for self-testing)	viola® Pregnancy Test (for detection of hCG (25 IU/l) in urine) viola® Pregnancy Test Strip (for detection of hCG (25 IU/l) in urine) viola® Pregnancy Test with Week Determination viola® GREEN Pregnancy Test (for detection of hCG (25 IU/l) in urine) viola® GREEN Pregnancy Test with Week Determination (for detection of hCG (25 IU/l) in urine) viola® Early Pregnancy Test (for detection of hCG (12 IU/l) in urine) viola® Early Pregnancy Test with Week Determination (for detection of hCG (12 IU/l) in urine) viola® GREEN Early Pregnancy Test (for detection of hCG (12 IU/l) in urine) viola® GREEN Early Pregnancy Test with Week Determination (for detection of hCG (12 IU/l) in urine) CARE diagnostica® Early Pregnancy Test (for detection of hCG (12 IU/l) in urine) CARE diagnostica® Early Pregnancy Test with Week Determination (for detection of hCG (12 IU/l) in urine) mediola Early Pregnancy Test (for detection of hCG (12 IU/l) in urine) YesNo Self-test Early Pregnancy (for detection of hCG (12 IU/l) in urine) Verival® / Verival® SELF-TEST Pregnancy (for detection of hCG (12 IU/l) in urine) viola® Super Early Pregnancy Test from day 8 (for detection of hCG (5 IU/l) in urine) CARE diagnostica® Super Early Pregnancy Test DUO from day 8 (for detection of hCG (5 IU/l) in urine)	Self testing, not Annex II



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**No. D4002000001**

Date 2016-11-04

Page 3 of 3

Product category	Product	Class
Tests for detection of hCG in urine (for self-testing)	ABBLO PHARMA® Early Pregnancy Test (for detection of hCG (5 IU/l) in urine)	Self testing, not Annex II
Tests for detection of hLH in urine (for self-testing)	viola® Ovulation Test (for detection of hLH (30 mIU/ml) in urine) YesNo Self-test Ovulation Test (for detection of hLH (30 mIU/ml) in urine)	Self testing, not Annex II
Tests for detection of urinary infection (for self-testing)	myCARE® Urinary Infection Health Care Test ApoLife® Harninfektion-Test YesNo Self-test Urinary tract infection Apoteket Self-test Urinary tract infection Ferlidona Urinary tract infection test Veroval® / Verival® SELF-TEST Urinary tract infection Ferlidona Urinary Infection Test CARE diagnostica® Self-test urinary tract Infection ABBLO PHARMA® Urinary tract infection test	Self testing, not Annex II
Tests for determination of cholesterol and LDL cholesterol in whole blood (for self-testing)	myCARE® Cholesterol and LDL Cholesterol Health Care Test myCARE® Cholesterol and LDL Cholesterol Health Care Test Card YesNo Self-Test Cholesterol Veroval® / Verival® SELF-TEST Cholesterol ApoLife® Cholesterin-Test Boots PHARMACEUTICALS Cholesterol Home Test Kit	Self testing, not Annex II
Vaginal pH tests (for self-testing)	viola® vaginal pH Test Veroval® SELF-TEST Vaginal infection prevention GINEintima Test pH	Self testing, not Annex II



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