

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

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

**Roemerstraße 8
2514 Traiskirchen
Austria**

for the scope

**tests for detection of Chlamydia trachomatis
tests for self-testing (hCG, hLH, FSH, vaginal pH, fecal occult blood,
Cholesterol, urinary infection)
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

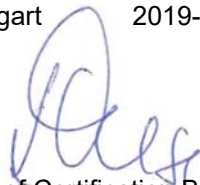
The mdc audit has proven that this quality system
meets all requirements according to

**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	2019-11-11
Valid until	2024-05-19
Registration no.	D4002000011
Report no.	P19-01755-164818
Stuttgart	2019-11-11



Head of Certification Body



Attachment of the certificate

No. D4002000011

Date 2019-11-11

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 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 SELFCheck Female Chlamydia test cyclotest® Chlamydia Rapid Test (for qualitative detection of Chlamydia trachomatis in vaginal swab specimen for self-testing) ChlamySal (for qualitative detection of Chlamydia trachomatis)	List B, Annex II
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)	Self testing not Annex II



Head of Certification Body



Attachment of the certificate

No. D4002000011

Date 2019-11-11

Page 2 of 3

Product category	Product	Class
Tests for detection of hCG in urine (for self-testing)	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) Veroval® SELF-TEST Pregnancy for detection of hCG (12 IU/l) in urine) medisur Autotest précoce de grossesse (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 from day 8 (for detection of hCG (5 IU/l) in urine) ABBLO PHARMA® Early Pregnancy Test (for detection of hCG (5 IU/l) in urine) besurence pregnancy week determination (for detection of hCG (12 IU/l) in urine)	Self testing not Annex II



Head of Certification Body



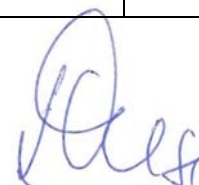
Attachment of the certificate

No. D4002000011

Date 2019-11-11

Page 3 of 3

Product category	Product	Class
Tests for detection of hLH in urine (for self-testing)	viola® Ovulation Test (for detection of hLH (30 mIU/ml) in urine)	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) SELFCheck Menopause Test (for detection of FSH (25 IU/l) in urine)	Self testing not Annex II
Vaginal pH tests (for self-testing)	viola® vaginal pH Test Veneris® TEST RAPID de pH	Self testing not Annex II
Tests for detection of fecal occult blood (for self-testing)	myCARE® Bowel Health Care Test myCARE® Colon Health Care Test myCARE® Blut im Stuhl-Test zur Darmkrebsvorsorge Selfdiagnostics Soolestiku polüübi (peitvere) Test SELFCheck Bowel Health Test	Self testing not Annex II
Tests for determination of cholesterol in whole blood (for self-testing)	myCARE® Cholesterol Health Care Test myCARE® Cholesterol Health Care Test Card Boots PHARMACEUTICALS Cholesterol Home Test Kit SELFCheck Cholesterol Level Test (for determination of cholesterol in whole blood)	Self testing not Annex II
Tests for detection of urinary infection (for self-testing)	myCARE® Urinary Infection Health Care Test Ferlidona Harnwegsinfektionstest Veroval® SELF-TEST Urinary tract infection CARE diagnostica® Self-test urinary tract Infection ABBLO PHARMA® Urinary tract infection test SELFCheck Urine Infection Test mediola Harninfektion Vorsorge Test	Self testing not Annex II



Head of Certification Body

