

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

**Testing devices for the detection of Chlamydia trachomatis as well as
rapid self-testing devices (Chlamydia trachomatis, hCG, hLH, vaginal pH,
fecal occult blood, urinary infection, cholesterol)
(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	2022-05-23
Valid until	2025-05-26
Registration no.	D4002000016
Report no.	P22-00002-238941
Stuttgart	2022-05-23


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

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Product category	Product	Class
Rapid immunochromatographic assay for the qualitative detection of Chlamydia trachomatis in endocervical swab specimen (for professional use)	chlamyCARE-C (REF 0702022- E, D, F; 490207-20- E, D, F)	List B, Annex II
Tests for the qualitative detection of Chlamydia trachomatis in vaginal swab specimen (for self-testing)	viola [®] Chlamydia Test (REF 972756-1P- D, E, PL, SE, NO, NL, IT-SIL, IS, LT, DE-MHF, SK, EE, HU, BG, HU-ALAB, PL-FARMA) ABBLO [®] PHARMA Chlamydia test (REF 972756-1P- ABBLO, FI-ABBLO) Veroval [®] SELF-TEST Chlamydia (REF 972756- CZSK-PH, NL-PH) MEDESIGN Chlamydia Rapid Test (REF 972756-1P- DE-MED) Veneris [®] Test for detection of infection with Chlamydia trachomatis (REF 972756-1P- RO-VENERIS) SELFCheck Female Chlamydia test (REF 972756-1P- 1ST) DE SOA TESTER Chlamydia Sneltest (REF 972756-1P- NL-TESTER) HORNYHIVE CHLAMYDIEN SCHNELLTEST (REF 972756-1P- DE-HORN) cyclotest [®] Chlamydia Rapid Test (REF Y972756- UEBE)	List B, Annex II





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Product category	Product	Class
Tests for the detection of (5 mIU/ml) hCG in urine (for self-testing)	viola® Super Early Pregnancy Test from day 8 (REF 973005- D, E, SRB, CH-U, SELF, RO-SUPER, NL, DE-MHF, SIHR, IT, BG, HU, HU-ALAB, PL-FARMA, GR-ACC, MK; 972992- D, SELF, LT, MK) CARE diagnostica® Super Early Pregnancy Test DUO from day 8 (REF 973005- BE-BOM) ABBLO® PHARMA Early Pregnancy Test (REF 973005- ABBLO, DE-GB-ABBLO, ES-GB-ABBLO, FI-ABBLO) Freyja Super Early Pregnancy Test (REF 972992- BE-Freya)	Self-testing not Annex II
Tests for the detection of (12 IU/l) hCG in urine (for self-testing)	viola® Early Pregnancy Test (REF 970202- D, E, GR, ARAB-E, IT, NL, MK; 972206- D, GR) MEDESIGN Early Pregnancy Test (REF 970202- DE-MED) Biopax Early Pregnancy Test (REF 970202- BE-BOM) viola® GREEN Early Pregnancy Test (REF 970202-ÖKO- D, FR) viola® Early Pregnancy Test with Week Determination (REF 972862- D, E, CH-U, SV, SRB, SELF, RO-SUPER, NL, PL-FARMA, MK; 972909- CH-U, SELF) Verova® SELF-TEST Pregnancy (REF 972862- ESPT-PH) viola® GREEN Early Pregnancy Test with Week Determination (REF 972862-ÖKO- D) Biopax Early Pregnancy Test with Week Determination (REF 972862- BE-BOM) medisur Autotest précoce de grossesse (REF 972862-ÖKO-FR- MS, -MS2) besurence pregnancy week determination (REF 972862-ARAB-BESURENC)	Self-testing not Annex II



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Product category	Product	Class
Tests for the detection of (25 IU/l) hCG in urine (for self-testing)	viola® Pregnancy Test (REF 970110- D, E) viola® GREEN Pregnancy Test (REF 970110- ÖKO-D) Freyja Regular Pregnancy Test (REF 970110- BE-Freyja) viola® Pregnancy Test Strip (REF 971247- D) viola® Pregnancy Test with Week Determination (REF 972800- D, E, CH-U, NL, MK) viola® GREEN Pregnancy Test with Week Determination (REF 972800- ÖKO-D)	Self-testing not Annex II
Tests for the detection of (30 mIU/ml) hLH in urine (for self-testing)	viola® Ovulation Test (REF 972077- D, E, SRB, BG, HU, HU-ALAB, MK; 972077- CH-U)	Self-testing not Annex II
Tests for the determination of vaginal pH (for self-testing)	viola® vaginal pH Test (REF 972763- 2- D, E, IT, SELF, SRB, BG, HU, HU-ALAB, NL, LT-EURO; 972763- 10-D; 972763- 3-D) MEDESIGN vaginaler pH Test (REF 972763- 3-DE-MED) Veneris® TEST RAPID de pH (REF 972763-RO-VENERIS) Vagiflor® care vaginaler pH Test (REF 972763- 3-DE-Vagi) CONSTANZE CARE Vaginaler pH Schnelltest (REF 972763-3-DE-CON) HORNYHIVE VAGINALER pH SCHNELLTEST (REF 972763-3-DE-HORN)	Self-testing not Annex II





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Product category	Product	Class
Tests for the detection of fecal occult blood (for self-testing)	myCARE® Bowel Health Care Test (REF 970165- E, IT-SIL, NL, SRB, DE-MHF, SK, HU) myCARE® Colon Health Care Test (REF 970165- SE) Selfdiagnostics Soolestiku polüübi (peitvere) Test (REF 970165- EST) DE MEDISCHE TESTER Darmen Gezondheids Test (REF 970165- NL-TESTER) myCARE® Blut im Stuhl-Test zur Darmkrebsvorsorge (REF 970166- D, BG, HU-ALAB) SELFCheck Bowel Health Test (REF 970166- 1ST)	Self-testing not Annex II
Tests for the detection of urinary infection (detection of leukocytes, nitrite and protein in human urine samples) (for self-testing)	myCARE® Urinary Infection Health Care Test (REF 970158- D, E, EST, SV, GR, NL, IT-SIL, IS, BG, HU, HU-ALAB, PL-FARMA, GR-ACC) Verova® SELF-TEST Urinary tract infection (REF 970158- CZSK-PH, ESPT-PH, NL-PH) SELFCheck Urine Infection Test (REF 970158- 1ST) HORNYHIVE HARNINFEKTION VORSORGETEST (REF 970158- DE-HORN) CARE diagnostica® Self-test urinary tract Infection (REF 970158- NORGE) ABBLO® PHARMA Urinary tract infection test (REF 970158- 3-ABBLO, 3-FI-ABBLO)	Self-testing not Annex II
Rapid enzymatic test for the semi-quantitative determination of total cholesterol levels in human whole blood (for self-testing)	myCARE® Cholesterol Health Care Test (REF 970264- D, E, SV, NL, IS) myCARE® Cholesterol Health Care Test Card (REF 972664- D, E, NL, BG, HU, IT, HU-ALAB, PL-FARMA) SELFCheck Cholesterol Level Test (REF 972664- 1ST) DE MEDISCHE TESTER Cholesterol Gezondheids Test (REF 972664- NL-TESTER) Boots PHARMACEUTICALS Cholesterol Home Test Kit (REF 21-06-094)	Self-testing not Annex II



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