

## DECLARATION OF CONFORMITY

CARE diagnostica Produktions- und Vertriebsgesellschaft m.b.H.  
Roemerstrasse 8, 2514 Traiskirchen, Austria

declare in sole responsibility that their range of In-vitro diagnostic medical devices listed in Appendix I comply with the Essential Requirements in Annex I of directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

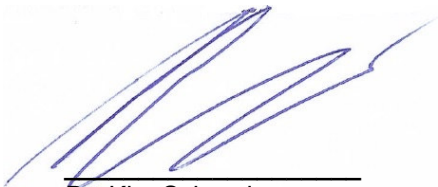
An EC Certificate (Registration no. **D4002000016**) was granted by notified body

mdc medical device certification GmbH  
Kriegerstraße 6, 70191 Stuttgart, Germany  
Identification number 0483

The conformity assessment procedure was carried out in accordance with Annex IV (excl. section 4 and 6) of Directive 98/79/EC.

The products are in conformity with harmonised standards listed in Annex "List of standards".

Traiskirchen, 2022-05-23



Dr. Kim Scheuringer  
Executive Manager

### Appendices:

- Appendix I: List of products (3 pages)
- Appendix II: List of standards applied in full or in part (1 page)

Document:	Revision:	Date of expiry:
DoC_CE0483 (1 page)	24	2025-05-26

## APPENDIX I

Appendix to document DoC\_CE0483 Revision 24

### List of products

#### A) Classification: list B, Annex II

##### Tests for qualitative detection of Chlamydia trachomatis

IVD for self-testing

Product	REF	Diagnostic components
viola <sup>®</sup> Chlamydia Test	972756-1P- D, E, PL, SE, NO, NL, IT-SIL, IS, LT, DE-MHF, SK, EE, HU, BG, HU-ALAB, PL-FARMA	1 test cassette, buffer (0.6 ml)
ABBLO <sup>®</sup> PHARMA Chlamydia test	972756-1P- ABBLO, FI-ABBLO	
Verova <sup>®</sup> SELF-TEST Chlamydia	972756- CZSK-PH, NL-PH	
medesign Chlamydia Rapid Test	972756-1P- DE-MED	
Veneris <sup>®</sup> Test for detection of infection with Chlamydia trachomatis	972756-1P- RO-VENERIS	
SELFCheck Female Chlamydia test	972756-1P- 1ST	
DE SOA TESTER Chlamydia Sneltest	972756-1P- NL-TESTER	
HORNHYVE CHLAMYDIEN SCHNELLTEST	972756-1P- DE-HORN	1 test cassette, buffer A (0.3 ml), buffer B (0.4 ml)
cyclotest <sup>®</sup> Chlamydia Rapid Test	Y972756- UEBE	

IVD for professional use

Product	REF	Diagnostic components
chlamyCARE-C	070202- E, D, F 490207- 20- E, D, F	20 test cassettes, 1 buffer A (5 ml), 1 buffer B (5 ml)

#### B) Classification: IVD for self-testing

##### Tests for detection of hCG (25 IU/l) in urine

Product	REF	Diagnostic components
viola <sup>®</sup> Pregnancy Test	970110- D, E	1 test stick
viola <sup>®</sup> GREEN Pregnancy Test	970110- ÖKO-D	
Freyja Regular Pregnancy Test	970110- BE-Freya	
viola <sup>®</sup> Pregnancy Test Strip	971247- D	1 test strip
viola <sup>®</sup> Pregnancy Test with Week Determination	972800- D, E, CH-U, NL, MK	1 test stick
viola <sup>®</sup> GREEN Pregnancy Test with Week Determination	972800- ÖKO-D	

##### Tests for detection of hCG (12 IU/l) in urine

Product	REF	Diagnostic components
viola <sup>®</sup> Early Pregnancy Test	970202- D, E, GR, ARAB-E, IT, NL, MK	1 test stick
medesign Early Pregnancy Test	970202- DE-MED	
Biopax Early Pregnancy Test	970202- BE-BOM	
viola <sup>®</sup> GREEN Early Pregnancy Test	970202-ÖKO- D, FR	
viola <sup>®</sup> Early Pregnancy Test	972206- D, GR	2 test sticks
viola <sup>®</sup> Early Pregnancy Test with Week Determination	972862- D, E, CH-U, SV, SRB, SELF, RO-SUPER, NL, PL-FARMA, MK	1 test stick
Verova <sup>®</sup> SELF-TEST Pregnancy	972862- ESPT-PH	
viola <sup>®</sup> GREEN Early Pregnancy Test with Week Determination	972862-ÖKO- D	
Biopax Early Pregnancy Test with Week Determination	972862- BE-BOM	
medisur Autotest précoce de grossesse	972862-ÖKO-FR- MS, -MS2	

besurence pregnancy week determination	<b>972862</b> -ARAB-BESURENC	
viola <sup>®</sup> Early Pregnancy Test with Week Determination	<b>972909</b> - CH-U, SELF	2 test sticks

#### Tests for detection of hCG (5 mIU/ml) in urine

Product	REF	Diagnostic components
viola <sup>®</sup> Super Early Pregnancy Test from day 8	<b>973005</b> - D, E, SRB, CH-U, SELF, RO-SUPER, NL, DE-MHF, SIHR, IT, BG, HU, HU-ALAB, PL-FARMA, GR-ACC, MK	2 test sticks
CARE diagnostica <sup>®</sup> Super Early Pregnancy Test DUO from day 8	<b>973005</b> - BE-BOM	
ABBLO <sup>®</sup> PHARMA Early Pregnancy Test	<b>973005</b> - ABBLO, DE-GB-ABBLO, ES-GB-ABBLO, FI-ABBLO	
viola <sup>®</sup> Super Early Pregnancy Test from day 8	<b>972992</b> - D, SELF, LT, MK	1 test stick
Freyja Super Early Pregnancy Test	<b>972992</b> - BE-Freya	

#### Tests for detection of hLH (30 mIU/ml) in urine

Product	REF	Diagnostic components
viola <sup>®</sup> Ovulation Test	<b>972077</b> - D, E, SRB, BG, HU, HU-ALAB, MK	5 test sticks, 1 test disc
viola <sup>®</sup> Ovulation Test	<b>972077</b> - CH-U	5 test sticks, 2 test discs

#### Tests for determination of vaginal pH

Product	REF	Diagnostic components
viola <sup>®</sup> vaginal pH Test	<b>972763</b> - 2- D, E, IT, SELF, SRB, BG, HU, HU-ALAB, NL, LT-EURO	2 applicators
	<b>972763</b> - 10-D	10 applicators
	<b>972763</b> - 3-D	3 applicators
medesign vaginaler pH Test	<b>972763</b> - 3-DE-MED	3 applicators
Veneris <sup>®</sup> TEST RAPID de pH	<b>972763</b> -RO-VENERIS	2 applicators
Vagiflor <sup>®</sup> care vaginaler pH Test	<b>972763</b> - 3-DE-Vagi	3 applicators
CONSTANZE CARE Vaginaler pH Schnelltest	<b>972763</b> - 3-DE-CON	3 applicators
HORNYHIVE VAGINALER pH SCHNELLTEST	<b>972763</b> - 3-DE-HORN	3 applicators

#### Tests for detection of fecal occult blood

Product	REF	Diagnostic components
myCARE <sup>®</sup> Bowel Health Care Test	<b>970165</b> - E, IT-SIL, NL, SRB, DE-MHF, SK, HU, BG	1 test cassette, 1 buffer (2.5 ml)
myCARE <sup>®</sup> Colon Health Care Test	<b>970165</b> - SE	
Selfdiagnostics Soolestiku polüübi (peitvere) Test	<b>970165</b> - EST	
DE MEDISCHE TESTER Darmen Gezondheids Test	<b>970165</b> - NL-TESTER	
myCARE <sup>®</sup> Blut im Stuhl-Test zur Darmkrebsvorsorge	<b>970166</b> - D, HU-ALAB	
SELFCheck Bowel Health Test	<b>970166</b> - 1ST	

#### Tests for determination of Cholesterol in whole blood

Product	REF	Diagnostic components
myCARE <sup>®</sup> Cholesterol Health Care Test	<b>970264</b> - D, E, SV, NL, IS	1 test disc
myCARE <sup>®</sup> Cholesterol Health Care Test Card	<b>972664</b> - D, E, NL, BG, HU, IT, HU-ALAB, PL-FARMA	1 test card
SELFCheck Cholesterol Level Test	<b>972664</b> - 1ST	
DE MEDISCHE TESTER Cholesterol Gezondheids Test	<b>972664</b> - NL-TESTER	1 test card
Boots PHARMACEUTICALS Cholesterol Home Test Kit	<b>21-06-094</b>	1 test card

**Tests for detection of urinary infection**

<b>Product</b>	<b>REF</b>	<b>Diagnostic components</b>
myCARE <sup>®</sup> Urinary Infection Health Care Test	<b>970158-</b> D, E, EST, SV, GR, NL, IT-SIL, IS, BG, HU, HU-ALAB, PL-FARMA, GR-ACC	2 test strips
Veroval <sup>®</sup> SELF-TEST Urinary tract infection	<b>970158-</b> CZSK-PH, ESPT-PH, NL-PH	
SELFCheck Urine Infection Test	<b>970158-</b> 1ST	
HORNYHIVE HARNINFEKTION VORSORGETEST	<b>970158-</b> DE-HORN	3 test strips
CARE diagnostica <sup>®</sup> Self-test urinary tract Infection	<b>970158-</b> NORGE	
ABBLO <sup>®</sup> PHARMA Urinary tract infection test	<b>970158-</b> 3-ABBLO, 3-FI-ABBLO	

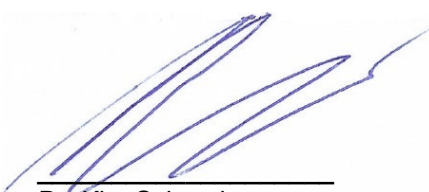
## APPENDIX II

Appendix to document DoC\_CE0483 Revision 24

### List of standards applied in full or in part

Norm / Standard	Bezeichnung / Title
EN ISO 13485 i.d.g.F.	Medizinprodukte – Qualitätsmanagementsysteme – Anforderungen für regulatorische Zwecke
EN 13532 i.d.g.F.	Allgemeine Anforderungen an In-vitro-Diagnostika zur Eigenanwendung
EN 13612 i.d.g.F.	Leistungsbewertung von In-vitro-Diagnostika
EN 13641 i.d.g.F.	Eliminierung oder Herabsetzung des von Reagenzien für in-vitro-diagnostische Untersuchungen ausgehenden Infektionsrisikos
EN 13975 i.d.g.F.	Probenahmeverfahren für die Annahmeprüfung von In-vitro-Diagnostika – Statistische Aspekte
EN ISO 14971 i.d.g.F.	Medizinprodukte- Anwendung des Risikomanagements auf Medizinprodukte
EN ISO 15223-1 i.d.g.F.	Medizinprodukte – Bei Aufschriften von Medizinprodukten zu verwendende Symbole, Kennzeichnung und zu liefernde Informationen – Teil 1: Allgemeine Anforderungen
EN ISO 17511 i.d.g.F.	In-vitro-Diagnostika – Messung von Größen in Proben biologischen Ursprungs – Metrologische Rückführbarkeit von Werten, die Kalibriermaterialien und Kontrollmaterialien zugeordnet sind
EN ISO 18113-1 i.d.g.F.	IVD – Bereitstellung von Informationen durch den Hersteller – Teil 1: Begriffe und allgem. Anforderungen
EN ISO 18113-2 i.d.g.F.	In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller – Teil 2: In-vitro-diagnostische Reagenzien für den Gebrauch durch Fachpersonal
EN ISO 18113-4 i.d.g.F.	In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller – Teil 4: Reagenzien für in-vitro-diagnostische Untersuchungen zur Eigenanwendung
EN ISO 23640 i.d.g.F.	In-vitro-Diagnostika - Haltbarkeitsprüfung von Reagenzien für in-vitro-diagnostische Untersuchungen
EN 62366-1 i.d.g.F.	Medizinprodukte - Teil 1: Anwendung der Gebrauchstauglichkeit auf Medizinprodukte
ISO TR 80002-2 i.d.g.F.	Medizinische Gerätesoftware - Teil 2: Validierung von Software zur Verwendung in der Qualitätssicherung für medizinische Geräte

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