

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that



savyonDIAGNOSTICS

**Savyon Diagnostics LTD.
3 Habosem Street
Ashdod, 7761003
Israel**

for the scope

**Test kits for the determination of antibodies to Chlamydia,
Test kits for the detection of Chlamydia antigen,
Test devices for detection of Chlamydia trachomatis DNA,
Rapid Vaginal Yeast Test for self-testing, Urinary Tract Infection Test for self-testing,
Rapid pregnancy (hCG, 12.5 mIU/ml) Tests for self-testing,
Rapid Ovulation (LH) Tests for self-testing
(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	2017-06-16
Valid until	2021-02-02
Registration no.	D1046300033
Report no.	P17-00695-97554
Stuttgart	2017-06-16

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. D1046300033

Date 2017-06-16

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Product category	Product	Class
Test devices for detection of Chlamydia trachomatis DNA	NanoCHIP® STI PLEX NanoCHIP® STI PLEX+	List B, Annex II
Test kits for the detection of Chlamydia antigen	QuickStripe CHLAMYDIA Ag QuickStripe CHLAMYDIA Ag with positive control	List B, Annex II
Test kits for the determination of antibodies to Chlamydia	SeroFIA CHLAMYDIA IgG, IgA, IgM SeroFIA CHLAMYDIA pneumoniae, psittaci, trachomatis SeroELISA CHLAMYDIA IgG, IgA, IgM SeroCT IgG, IgA SeroCT RT IgG, IgA SeroCP IgG, IgA, IgM SeroCP RT IgG, IgA, IgM SeroCP QUANT IgG, IgA IPAzyme CHLAMYDIA IgG/IgA, IgM	List B, Annex II
Rapid pregnancy (hCG, 12.5 mIU/ml) Tests for self-testing	Savvycheck™ Pregnavit®-Schwangerschaftstest Zwangerschapstest PCH Zwangerschapstest Sandoz®	Self testing, not Annex II
Rapid Ovulation (LH) Tests for self-testing	Savvycheck Ovulation Predictor Ovulatiestest PCH	Self testing, not Annex II
Rapid Vaginal Yeast Test for self-testing	Savvycheck™ - Rapid Vaginal Yeast Test for self-testing - OTC KANDIDA TEST - Kvasinkovy Test (distributed by Monsea Ltd., Slovakia) GENITEST VAGINALAS KANDIDOZES TESTS - OTC (distributed by GeniTest, SIA Latvia) EXACTO® Mycose vaginale - OTC (distributed by BIOSYNEX SA, France)	Self testing, not Annex II
Urinary Tract Infection Test for self-testing	URISCREEN URINFEKT Test	Self testing, not Annex II



Head of Certification Body

