EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

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 and
Chlamydia trachomatis DNA,
Rapid self-testing devices for the detection of Vaginal Yeast,
hCG, LH, SARS-CoV-2 Ag
(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	2022-02-17
Valid until	2025-05-26
Registration no.	D1046300043
Report no.	P21-01398-213959
Stuttgart	2022-02-17

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-BS-247.10.05

mdc medical device certification GmbH
Kriegerstraße 6

Attachment of the certificate

No. D1046300043 Date 2022-02-17 Page 1 of 1

Product category	Product	Class
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
Test kits for the detection of Chlamydia antigen	QuickStripe CHLAMYDIA Ag QuickStripe CHLAMYDIA Ag with positive control	List B, Annex II
Test devices for detection of Chlamydia trachomatis DNA	NanoCHIP® STI PLEX NanoCHIP® STI PLEX+ Savvygen™ STI CT/NG/TV	List B, Annex II
Rapid Pregnancy (hCG, 10 mIU/ml) Test for self-testing	Savvycheck™ Early Pregnancy Test Zwangerschapstest Sandoz® REF. 42015-P15 Teva Zwangerschapstest Ultra Sensitive Ratiopharm Schwangerschafts-Frühtest	Self-testing not Annex II
Rapid Ovulation (LH) Tests for self-testing	Savvycheck Ovulation Predictor	Self-testing not Annex II
Rapid Vaginal Yeast Test for self-testing	Savvycheck™ - Rapid Vaginal Yeast Test for self-testing – OTC Savvycheck™ Intim Candida - OTC (distributed by VITAMIN STATION KFT., Hungary) 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
Rapid SARS-CoV-2 antigen tests for self-testing in nasal swab samples	Savvycheck™ SARS-CoV-2 Ag (REF 42014-P02) RAPiDgen SARS-CoV-2 Ag Test (REF 42014-P03)	Self-testing not Annex II

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Supplement to the Certificate
according to 98/79/EC, Annex IV, excluding 4 and 6

Manufacturer	Savyon Diagnostics Ltd.
Certificate	No. D1046300043 Date: 2022-02-17 Test kits for the determination of antibodies to Chlamydia, Test kits for the detection of Chlamydia antigen and Chlamydia trachomatis DNA, Rapid self-testing devices for the detection of Vaginal Yeast, hCG, LH, SARS-CoV-2 Ag (see attachment)
Products concerned	Test kits for the determination of antibodies to Chlamydia, Test kits for the detection of Chlamydia trachomatis DNA, Rapid self-testing devices for the detection of Vaginal Yeast, hCG
Intended change	Omission of the following products from the product groups: – Test kits for the determination of antibodies to Chlamydia: SeroCT RT IgG, IgA; SeroCP RT IgG, IgA, IgM – Test devices for detection of Chlamydia trachomatis DNA: NanoCHIP® STI PLEX; NanoCHIP® STI PLEX+ – Rapid Pregnancy (hCG, 10 mIU/ml) Test for self testing: Zwangerschapstest Sandoz® REF. 42015-P15 – Rapid Vaginal Yeast Test for self-testing: 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)
Review report no.	P22-01651-251633

The intended change is in compliance with the requirements of the Directive 98/79/EC.
This supplement is valid only in conjunction with the aforementioned Certificate.
The aforementioned Certificate is valid only in conjunction with this supplement.

This supplement is valid until: 2025-05-26
Registration no.: D1046300044
Stuttgart 2022-11-04

Head of Notified Body

medical device certification mdc

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