



Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device
We, Savyon Diagnostics Ltd.
3, Habosem Street, Ashdod, 77610, Israel
Tel.: +972.8.8562920 Fax: +972.8.8523176 E-mail: info@savyondiagnosics.com

Declare under our sole responsibility that the following self testing IVD medical device, not covered by Annex II:

Savycheck -Pregnancy Test - OTC (Savyon Brand Name)
Pregnavit-Schwangerschaftstest -OTC (Distributed by Ratiopharm GmbH, Austria)
Zwangerschapstest PCH - OTC (Distributed by Teva Nederland, BV, Holland)
Zwangerschapstest Sandoz- OTC (Distributed by Sandoz BV, Holland)
Savycheck -Ovulation Predictor - OTC (Savyon Brand Name)
Savycheck™ - Rapid Vaginal Yeast Test for self-testing -OTC (Savyon Brand Name)
KANDIDA TEST-Kvasinkovy Test- OTC (Distributed by Monsea Ltd., Slovakia)
GENITEST VAGINALAS KANDIDOZES TESTS-OTC (Distributed by GeniTest, SIA Latvia)
EXACTO® Mycos vaginale - OTC (Distributed by BIOSYNEX SA, France)
URISCREEN
URINFEKT TEST (OTC) Distributed by Monsea Ltd., Slovakia

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Conformity assessment was performed according to Annex IV - excluding Section 4 and 6 by

mdc medical device certification GmbH (0483)
Kriegerstrasse 6
D-70191 Stuttgart, Germany
Phone +49-(0)-711-253597-0
Fax +49-(0)-711-253597-10
e-mail: mdc@mdc-ce.de
website: <http://www.mdc-ce.de>

The current applicable standards were used to prove the products conformity with the essential requirements of the above directive as defined in the Savyon Diagnostics Ltd., internal procedure QA-927.

Savyon Diagnostics Ltd has a Quality System in place based on EN ISO 13485:2012.

Signatory established within the EU who has been empowered to enter into commitments on our behalf :

European Authorized Representative (EC REP)

Obelis S.A. (O.E.A.R.C.)

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Mr. Gideon Elkayam

Position: C.E.O.

Signature:

Date: 2017.05.10

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Name: Estee Sagiv (Regulatory Affairs)

Email : esti@savyondiagnositics.com

Signature: 

Expiry Date: 2021.02.02

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סביון דיאגנוסטיקה בע"מ


G. ELKAYAM
C.E.O.

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