



## 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:

**Savvycheck™ - Rapid Vaginal Yeast Test for self-testing -OTC (Savyon Brand Name)**  
**KANDIDA TEST-Kvasinkovy Test- OTC (Distribted by Monsea Ltd., Slovakia)**  
**GENITEST VAGINALAS KANDIDOZES TESTS-OTC (Distributed by GeniTest, SIA Latvia)**  
**EXACTO® Mycos vaginale - OTC (Distributed by BIOSYNEX SA, France)**

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.)

Registered address:

34 Av. De Tervuren, bte 44

B-1040 Brussels, Belgium

Corporate office:

53, Boulevard Général Wahis

B-1030 Brussels, Belgium

Phone : +32.2.732.59.54

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E-mail : [mail@obelis.net](mailto:mail@obelis.net)

Mr. Gideon Elkayam

Position: C.E.O.

Signature:

Savyon Diagnostics Ltd.

3 Habosem Street, Ashdod,

77610, Israel

Tel.: +972.8.8562920

Fax: +972.8.8523176

Name: Estee Sagiv (Regulatory Affairs)

Email : [esti@savyondiagnosics.com](mailto:esti@savyondiagnosics.com)

Signature:

**SAVYON DIAGNOSTICS LTD**

**סביון דיאגנוסטיקה בע"מ**

Date: 2017.05.10

Expiry Date: 2021.02.02



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

### **Savycheck -Ovulation Predictor - OTC (Savyon Brand Name)**

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

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Mr. Gideon Elkayam

Position: C.E.O.

Signature:

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Name: Estee Sagiv (Regulatory Affairs)

Email : [esti@savyondiagnosics.com](mailto:esti@savyondiagnosics.com)

Signature:

SAVYON DIAGNOSTICS LTD

סביון דיאגנוסטיקה בע"מ

Date: 2017.05.10

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G.E.KAYAM  
C.E.O.

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