



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 -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

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

Mr. Gideon Elkayam

Position: C.E.O.

Signature:

Savyon Diagnostics Ltd.

3 Habosem Street, Ashdod,

77610, Israel

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Name: Estee Sagiv (Regulatory Affairs)

Email : esti@savyondiagnosics.com

Signature:

OBELIS s.a. - O.E.A.R.C

Registered address :

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1030 Bruxelles

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SAVYON DIAGNOSTICS LTD

סביון דיאגנוסטיקה בע"מ

Date: 2017.05.10

Expiry Date: 2021.02.02