



## Declaration of Conformity

According to annex IV 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: [esti@savyondiagnosics.com](mailto:esti@savyondiagnosics.com)

Declare under our sole responsibility that the following in vitro diagnostic medical devices covered by annex II List B:

**List of Products:**

SeroCT IgG  
SeroCT IgA  
SeroCT IgG(RT)  
SeroCT IgA(RT)  
SeroCP IgG  
SeroCP IgM  
SeroCP IgA  
SeroCP IgG(RT)  
SeroCP IgM(RT)  
SeroCP IgA(RT)  
SeroCP Quant IgG  
SeroCP Quant IgA  
SeroFIA Chlamydia IgG  
SeroFIA Chlamydia IgM  
SeroFIA Chlamydia IgA  
SeroFIA C.pneumoniae  
SeroFIA C.trachomatis  
SeroFIA C.psitacci  
SeroELISA Chlamydia IgG  
SeroELISA Chlamydia IgA  
SeroELISA Chlamydia IgM  
IPAzyme Chlamydia IgG/IgA  
IPAzyme Chlamydia TRUE IgM  
QuickStripe Chlamydia Ag  
QuickStripe Chlamydia Ag including Positive Control  
NanoCHIP ® STI PLEX  
NanoCHIP ® STI PLEX +

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 .3

**Notified Body**

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](mailto: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:

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B-1030 Brussels, Belgium

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Mr. Gideon Elkayam

Position: C.E.O.

Signature:

Savyon Diagnostics Ltd.

3 Habosem Street, Ashdod,

77610, Israel

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Fax: +972.8.8523176

Name: Estee Sagiv (Regulatory Affairs)

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

Signature:

*Esti*

SAVYON DIAGNOSTICS LTD

סביון דיאגנוסטיקה בע"מ

Date: 2016.02.03

Expiry Date: 2021.02.02

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

Registered address :

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