Declaration of Conformity

According to Annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device

We,

Savyon Diagnostics Ltd.
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Tel.: +972.8.8562920 Fax: +972.8.8523176 E-mail: info@savyondiagnostics.com

Declare under our sole responsibility that the following IVD medical devices, covered by Annex II:

Reference number:	List of Products:
A181-01M, B181-01M, A181-01D	SeroCT IgG
A183-01M, B183-01M, A183-01D	SeroCT IgA
1181-01D	SeroCT IgG(RT)
1183-01D	SeroCT IgA(RT)
A191-01M, B191-01M, A191-01D	SeroCP IgG
A192-01M, B192-01M, A192-01D	SeroCP IgM
A193-01M, B193-01M, A193-01D	SeroCP IgA
1191-01D	SeroCP IgG(RT)
1192-01D	SeroCP IgM(RT)
1193-01D	SeroCP IgA(RT)
A291-01	SeroCP Quant IgG
A293-01	SeroCP Quant IgA
511-01	SeroFIA Chlamydia IgG
512-01	SeroFIA Chlamydia IgM
513-01	SeroFIA Chlamydia IgA
590-01	SeroFIA C.pneumoniae
580-01	SeroFIA C.trachomatis
570-01	SeroFIA C.psitacci
A111-01D	SeroELISA Chlamydia IgG
A113-01D	SeroELISA Chlamydia IgA
A112-01D	SeroELISA Chlamydia IgM
011-01	IPAzyme Chlamydia IgG/IgA
012-01	IPAzyme Chlamydia TRUE IgM
41101	QuickStripe Chlamydia Ag
41115	QuickStripe Chlamydia Ag including Positive Control
899055	NanoCHIP ® STI PLEX
899056	NanoCHIP ® STI PLEX +
618-01	Savvygen STI CT/NG/TV

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 (except point 4 & 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

CE Certificate's details:
No.: **D1046300041**
Date of Issue: **2021-02-03**

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 entitled: List of Standards.

Corporate Contact Information
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Email : esti@savyondiagnostics.com
Signature :
Date : 2020-12-15
Valid till: 2024-02-02
Stamp :

Esti
SAVYON DIAGNOSTICS LTD
סביון דיאגנוסטיקה בע"מ

European Authorized Representative:
Registered Address:
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Representative: Mr. Gideon ELKAYAM (CEO)

Form No.:QA-927
Name of Form: LIST OF STANDARDS

LIST OF STANDARDS

Code	Name	Savyon Diagnostics' SOPs
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	QA-0001- QA-0020, QA-1001,1002, 1003,1004, 1068,1069, RD-3001, 3002, 3006, 3008, 3010, 3012, 3013 3016
EN ISO 13485:2016/AC:2018		
EN ISO 15223-1: 2016	Medical Devices. Symbols To Be Used With Medical Device Labels, Labelling And Information To Be Supplied. Part 1: General Requirements (ISO 15223-1:2016, Corrected version 2016-12-15)	QA-1011 RD-3012
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)	RD-3011
Directive 98/79/EC : 1998	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998, on the in-vitro diagnostic medical device.	QA-0001- QA-0020, QA-1003,1004, 1067, 1068 RD-3002, 3006, 3008, 3009, 3010, 3013
Directive IVDR 2017/746 EU	REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices	Directive IVDR 2017/746 EU was published 05.2017 and will go in effect 05.2022 repealing Directive 98/79/EC and Commission Decision 2010/227/EU
21 CFR PART 809 and 820 04.2011	QUALITY SYSTEM REGULATION (QSR)	QA-0001- QA-0020, QA-1001,1004, 1003 ,1069 RD-3001, 3002, 3006, 3008, 3009, 3010, 3012, 3013
Japanese IVD QMS 2010	Japanese IVD QMS (MHLW Ministerial Ordinance No.169)	QA-0001- QA-0020, QA-1001-1004, 1068,1069 RD-3001, 3002, 3006, 3008, 3010, 3012, 3013.
EN 13612: 2002/AC: 2002	Performance evaluation of in vitro diagnostic medical devices	QA-1010, 1069
EN 13641: 2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents	QC-3104
EN ISO 23640:2015	In vitro diagnostics medical devices – Evaluation of stability of in vitro diagnostics reagent.	QA-3104
MEDDEV 2.12-1 rev 8:01/2013	Guidelines on a medical devices vigilance system	QA-1003 QA-1003F1 QA-1003F2,
EN 13532: 2002	General requirements for in vitro diagnostics medical devices for self- testing.	
	In vitro diagnostic medical devices — Information supplied by the manufacturer	QA-1011

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Code	Name	Savyon Diagnostics' SOPs
EN ISO 18113-1: 2011	(labeling)- Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)	
EN ISO 18113-2: 2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling)- Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)	QA-1011
EN ISO 18113-3: 2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling)- Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)	QA-1011
EN ISO 18113-4: 2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling)- Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)	QA-1011
NB-MED/2.5.1/Rec6	Technical Docomentation	QA-1076
Z1.4-2003 (R2013)	Sampling procedures and tables for inspection by attributes	910026.B
EN13975:2003	Sampling procedures used for acceptance testing in vitro diagnostics medical devices – statistical aspects	QA-1024