CE

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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Declare under our sole responsibility that the following self-testing in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

Reference number:	List of Products:
42014-P02	*Savvycheck™ SARS-CoV-2 Ag (OTC-Savyon Brand Name)*
42014-P03	*RAPiDgen SARS-CoV-2 Ag Test (OTC-Distributed by Adaltis, S.r.l, Italy)*
42011	*Savvycheck™ Ovulation Predictor (OTC-Savyon Brand Name)*
42013	*Savvycheck™ Vaginal Yeast Test (OTC-Savyon Brand Name)*
42013-P06	*Savvycheck™ Intim Candida (OTC-Distributed by VITAMIN STATION KFT, Hungary)*
42013-P10	*KANDIDA TEST Kvasinkovy Test (OTC-Distributed by Monsea Ltd,Slovakia)*
42013-P14	*GENITEST VAGINALAS KANDIDOZES TESTS (OTC-Distributed by GeniTest,SIA, Latvia)*
42013-P15	*EXACTO MYCOSE VAGINALE (OTC-Distributed by BIOSYNEX-FRANCE)*
A42015-P01, B42015-P01	*Savvycheck™ Early Pregnancy Test (OTC-Savyon Brand Name)*
A42015-P12, B42015-P12	*Teva Zwangerschapstest Ultra Sensitive (OTC-Distributed by Teva Nederland, BV,Holland)*
A42015-P15	*Zwangerschapstest Sandoz (OTC-Distributed by Sandoz BV,Holland)*
A42015-P14, B42015-P14	*Ratiopharm Schwangerschafts-Frühtest (OTC-Distributed by Ratiopharm GmbH, Austria)*

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

Undersigned declares to fulfill the obligations imposed by Annex IV except point 4 & 6:

- availability of the technical documentation set in Annex IV (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex IV section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex IV section 5).

Conformity assessment was performed according to Article 9 (7) and Annex IV. As mentioned in EC Certificate issued by mdc medical device certification GmbH (0483)
Kriegerstrasse 6
D-70191 Stuttgart.Germany
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e-mail: mdc@mdc-ce.de
website: http://www.mdc-ce.de

CE Certificate's details:
No.: **D1046300043**
Date of Issue: **2022-02-17**

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.

The QA-927 List of Standards is attached.

Corporate Contact Information

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Date : 2022-02-17
Valid till : 2024-02-02

Esti
SAVYON DIAGNOSTICS LTD
סביון דיאגנוסטיקה בע"מ

European Authorized Representative:
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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 **EN ISO 13485:2016/AC:2018**	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 15223-1: 2016 **EN ISO 15223-1: 2021***	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 **EN ISO 14971:2019****	Medical devices - Application of risk management to medical devices.	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.	

Code	Name	Savyon Diagnostics' SOPs
EN ISO 18113-1: 2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labeling)- Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)	QA-1011
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 Documentation	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

** Several new symbols have been added and the definition of existing symbols updated, taking into account manufacturer and user needs and the evolving regulation of medical devices.*

*** Updated version specifies how to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. Suggested "State-of-the-art" to conform with the present Directive.*

Code	Name	Savyon Diagnostics' SOPs
COVID-19		
MDCG 2021-21	Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices	August 2021
MDCG 2021-7	Notice to manufacturers and authorized representatives on the impact of genetic variants on SARS-COV-2 in vitro diagnostic medical devices	May 2021
MDCG 2021-2	Guidance on state of the art of COVID-19 rapid antibody tests	March 2021

Directive IVDR 2017/746 EU-GUIDANCE

Reference	Title	Publication
MDCG 2019-7	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)	June 2019
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies	April 2020
MDCG 2020-16	Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746	November 2020
MDCG 2021-4	Application of transitional provisions for certification of class D in vitro diagnostic medical devices according to Regulation (EU) 2017/746	April 2021
MDCG 2021-22	Clarification on "first certification for that type of device" and corresponding procedures to be followed by notified bodies, in context of the consultation of the expert panel referred to in Article 48(6) of Regulation (EU) 2017/746	August 2021

Date	Name of corrector	Version No.	Details of correction (including Chapter, No)	Reasons of correction	Training need
22.11.05	ESTI	01	Forwarding to the form QA-927		NO
26.02.09	ESTI	02	EN ISO ,Updating EN 980:2008 14971:2007		NO
27.1.10	ESTI Nuphar Metsuyanim	03	Uupdating: *LIST OF STANDARDS* I/2010 Adding reference to the numbers of the relevant SOP		NO
16.02.10	ESTI	04	Updating: EN ISO 9001:2008, EN ISO 13485:2003/AC:2009; EN ISO 14971:2009		NO
12.01.11	ESTI	05	Updating: MEDDEV 2.12-1 rev 6 :2009		NO
11.1.12	ESTI	06	EN 375: 2001& EN 376: 2002 (till 31/12/2012)	reminder	NO
01.05.12	ESTI	07	Updating: MEDDEV 2.12-1 rev 7 :03/2012		NO
27.12.12	ESTI	08	Add EN ISO 188113-1:2011 Replace En 375-2001with EN ISO 188113-2:2011 Add EN ISO 188113-3:2011 Replace En 375-2001with EN ISO 188113-2:2011 Add BS EN ISO 13485: 2012 Add NB-MED/2.5.1/Rec5		Management Review jan.2013
14.02.13	ESTI	09	EN 15223-1:2012 to replace EN 980:2008	UPDATED	NO
17.02.14	ESTI	10	Vigellanc MEDDEV 2.12- 1 rev_8 replace rev_7 01-2013	UPDATED	NO
27.10.14	ESTI	11	Add EN ISO 18113-5:2011	UPDATED	NO
03.03.15	ESTI	12	Updated: 21 CFR PART 820 06.2011; QUALITY SYSTEM, Z1.4-2003 (R2013)- Sampling procedures and tables for inspection by attributes REGULATION (QSR)	UPDATED	NO
20.12.15	ESTI	13	Updating: remove standards of Canada	UPDATED	NO
27.12.15	ESTI	14	Updating NB-MED/2.5.1/Rec	UPDATED	NO

Date	Name of corrector	Version No.	Details of correction (including Chapter, No)	Reasons of correction	Training need
05.01.16	ESTI	15	Updating: Add an ISO :90012015 & EN980	Updated	NO
04.04.16	ESTI	16	Updating: EN ISO 9001:2008' (ERRORE)	Updated	NO
01.06.16	ESTI	17	Updating: EN ISO 13485:2012 Japanese IVD QMS 2010	Updated	NO
13.02.17	ESTI	18	Adding EN 13975:2003	Updated	NO
31.10.17	ESTI	19	Updating: stability EN ISO 23640:2015	Updated	NO
26.11.18	ESTI	20	Updating: EN ISO 13485:2016 Cancelled EN ISO 9001:2008	Updated	NO
08.01.19	ESTI	21	Updating: Delete EN 980:2008	Updated	NO
02.01.2020	ESTI	22	Addition of Directive IVDR 2017/746 EU	Updated	NO
29.10.2020	ESTI	23	Updating: Delete EN 13640:2002 Cancelled	Updated	NO
23.12.2021	ESTI	24	Addition of EU-Guidance for COVID-19 Addition of EU-Guidance for Directive IVDR 2017-746	Updated	NO
05.01.2022	ESTI	25	Addition of EN ISO 15223-1: 2021* and EN ISO 14971:2019**, which are updated versions that are not harmonized to the Directive 98/79/EC: 1998	Updated	NO