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, 7761003, Israel
Tel.: +972.8.8562920 Fax: +972.8.8523176 E-mail: info@savyondiagnostics.com

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

Reference number:	List of Products:
A42010-P01, B42010-P01	*Savvycheck™ -Pregnancy Test - OTC (Savyon Brand Name)*
A42010-P14, A42010-P14	*Pregnavit-Schwangerschaftstest -OTC (Distributed by Ratiopharm GmbH, Austria*
A42010-P12, B42010-P12	*Zwangerschapstest PCH - OTC (Distributed by Teva Nederland, BV, Holland)*
A42010-P15, A42010-P15	*Zwangerschapstest Sandoz- OTC (Distributed by Sandoz BV, Holland)*
42011	*Savvycheck™ -Ovulation Predictor - OTC (Savyon Brand Name)*
42013	*Savvycheck™ - Vaginal Yeast Test -OTC (Savyon Brand Name)*
42013-P10	*KANDIDA TEST-Kvasinkovy Test- OTC (Distribted 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*
101-01	*URISCREEN*
42014	*URINFEKT TEST (OTC) Distributed by Monsea Ltd., Slovakia*
A42015-01, B42015-01	*Savvycheck™ Early Pregnancy Test-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 (except point 4 & 6) by
mdc medical device certification GmbH (0483)
Kriegerstrasse 6
D-70191 Stuttgart.Germany
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CE Certificate's details:
No.: **D1046300037**
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Our current Quality System is formatted to international standards:

	Code	Name
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
2	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)
3	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
4	EN 13612: 2002/AC: 2002	Performance evaluation of in vitro diagnostic medical devices
5	EN 13641: 2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
6	EN ISO 23640:2015	In vitro diagnostics medical devices – Evaluation of stability of in vitro diagnostics reagent. Stability testing of in vitro diagnostic reagents
7	EN 13532: 2002	General requirements for in vitro diagnostics medical devices for self- testing.
8	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)
9	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)
10	Z1.4-2003 (R2013)	Sampling procedures and tables for inspection by attributes
11	EN13975:2003	Sampling procedures used for acceptance testing in vitro diagnostics medical devices –statistical aspects

Corporate Contact Information

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Date : 9.1.2019
Stamp :

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