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 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
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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 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)
8	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)
9	Z1.4-2003 (R2013)	Sampling procedures and tables for inspection by attributes
10	EN13975:2003	Sampling procedures used for acceptance testing in vitro diagnostics medical devices –statistical aspects

Corporate Contact Information

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Date : 09/11/2019
Stamp :

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