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DECLARATION OF CONFORMITY

DoC#: TF-1633, Rev 04.1

Legal Manufacturer: Innovacon, Inc.
Legal Manufacturer's Address: 9975 Summers Ridge Road
San Diego, CA 92121 USA

Declares that the product

Product Name	Model(s)
SureStep™ Multi-Drug One Step Multi-Line Screen Test Device (Urine)	DOA-135-051 DOA-155-111 DOA-155-151 DOA-155-191 DOA-165-071 DOA-165-081 DOA-165-171 DOA-175-011 DOA-175-031 DOA-175-071 DOA-185-051 DOA-185-061 DOA-185-091 DOA-195-061 DOA-1105-011 DOA-1105-041 DOA-1105-091 DOA-1105-111 DOA-1115-021 DOA-1115-031 DOA-1125-011 DOA-1125-041
SureStep™ Urine Drug Test Cassette	DOA-125-031 DOA-145-081 DOA-145-091 DOA-155-191 DOA-155-371 DOA-165-021 DOA-165-201 DOA-1105-031 DOA-1115-021

as described above are in conformity with the requirements of the standards listed in Appendix 1, Applicable Standards and Guidelines.

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Additional Information:

EC Representative's Name: EC Representative's Address:	Medical Device Safety Service GmbH Schiffgraben 41 30175 Hannover, Germany
Manufacturing Site:	ABON Biopharm (Hangzhou) Co., Ltd. #198, 12th Street East Hangzhou Economic and Technological Development Area 310018 Hangzhou, PR China
Management System:	MAN-003, Quality System Manual
Quality System Certificate No:	SX 2236944-1
Conformity Pathway:	Annex III
Classification:	Article 9, Section 1, Other IVD
EDMA Code:	12.70.09.70.00 – Multiple Drugs of Abuse – Toxicology Rapid Test

This Declaration of Conformity is issued under the sole responsibility of Innovacon, Inc. I, the undersigned, hereby declare on behalf of the manufacturer, Innovacon, Inc., that the medical devices specified above conform with the Directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements.

Crystal Lee

Crystal Lee
Specialist II, Regulatory Affairs

San Diego, California, USA
Date: July 18, 2022

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Appendix 1 to DOC # TF-1633		
Applicable Standards and Guidelines		
Category	**Name**	**Number: Date Issued**
General	In Vitro Diagnostic Device Directive	98/79/EC: 27 Oct 1998
	Medical Devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016 + A11:2021
Risk	Medical Devices – Application of risk management to medical devices	EN ISO 14971:2019+ A11:2021
	Medical Devices – Application of usability engineering to medical devices	EN 62366:2015
Labeling	Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements	EN 15223-1:2021
	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements	EN ISO 18113-1:2011
	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use	EN ISO 18113-2:2011
Performance	Performance evaluation of in vitro diagnostic medical devices	EN 13612:2002/AC:2002
	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents	EN ISO 23640:2015

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