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DECLARATION OF CONFORMITY

DoC#: TF-1630, Rev 03.2

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

Declares that the product
Product Name and Model(s)

DTH-101	Innovacon™ THC One Step Marijuana Test Strip (Urine) SureStep™ THC One Step Marijuana Test Strip (Urine) SureStep™ THC 50 Urine Drug Test Strip
DTH-102	Innovacon ™ THC One Step Marijuana Test Device (Urine) InstAlert ™ THC One Step Marijuana Test Device (Urine) SureStep ™ THC One Step Marijuana Test Device (Urine) SureStep™ THC 50 Urine Drug Test Cassette
DTH-B101	SureStep™ THC 150 Urine Drug Test Strip
DTH-C101	SureStep™ THC 20 One Step Marijuana Test Strip (Urine) SureStep™ THC 20 Urine Drug Test Strip

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

Additional Information:

EC Representative's Name: Medical Device Safety Service GmbH
EC Representative's Address: Schiffgraben 41
30175 Hanover, 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: 12.70.09.05.00 – Cannabinoids - Rapid Test

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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

Appendix 1 to DOC # TF-1630		
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	Symbols for use in the labeling of medical devices	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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