



## DECLARATION OF CONFORMITY

DoC#: TF-1616, 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 and Model(s)**

DCO-101	Innovacon™ COC One Step Cocaine Test Strip (Urine) SureStep™ COC One Step Cocaine Test Strip (Urine) SureStep™ COC 300 Urine Drug Test Strip
DCO-102	Innovacon™ COC One Step Cocaine Test Device (Urine) InstAlert™ COC One Step Cocaine Test Device (Urine) SureStep™ COC One Step Cocaine Test Device (Urine) SureStep™ COC 300 Urine Drug Test Cassette
DCO-U101	SureStep™ COC 150 One Step Cocaine Test Strip (Urine) SureStep™ COC 150 Urine Drug Test Strip
DCO-U102	SureStep™ COC 150 Urine Drug Test Cassette

**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, 12<sup>th</sup> 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:** 12.70.09.06.00 – Cocaine + Cocaine Metabolites – 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

Appendix 1 to DOC # TF-1616		
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