



## DECLARATION OF CONFORMITY

DoC#: TF-1625, Rev 04.2

**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)**

DOP-101	Innovacon™ OPI One Step Opiates Test Strip (Urine) SureStep™ OPI One Step Opiates Test Strip (Urine) SureStep™ OPI 2000 Urine Drug Test Strip
DOP-102	InstAlert™ OPI One Step Opiates Test Device (Urine) SureStep™ OPI One Step Opiates Test Device (Urine) SureStep™ OPI 2000 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:** 12.70.09.08.00 – Opiates - 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.

  
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Crystal Lee  
Specialist II, Regulatory Affairs

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

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Appendix 1 to DOC # TF-1625		
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