



DECLARATION OF CONFORMITY

DoC#: TF-1615, 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)

DBZ-101	Innovacon™ BZO One Step Benzodiazepines Test Strip (Urine) SureStep™ BZO One Step Benzodiazepines Test Strip (Urine) SureStep™ BZO 300 Urine Drug Test Strip
DBZ-102	Innovacon™ BZO One Step Benzodiazepines Test Device (Urine) InstAlert™ BZO One Step Benzodiazepines Test Device (Urine) SureStep™ BZO One Step Benzodiazepines Test Device (Urine) SureStep™ BZO 300 Urine Drug Test Cassette
DBZ-A101	SureStep™ BZO 200 One Step Benzodiazepines Test Strip (Urine) SureStep™ BZO 200 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: 12.70.09.04.00 – Benzodiazepines – 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-1615		
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