Abbott

DECLARATION OF CONFORMITY

DoC#: TF-1629, Rev 04

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)

DTC-101	SureStep™ TCA One Step Tricyclic Antidepressants Test Strip (Urine)
DTC-102	SureStep™ TCA One Step Tricyclic Antidepressants Test Device (Urine) SureStep™ TCA 1000 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: EC Representative's Address:	Medical Device Safety Service GmbH 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 60149668 0001, valid until 2021-08-24
Conformity Pathway:	Annex III
Classification:	Article 9, Section 1, Other IVD
EDMA Code:	12.70.09.10.00 – Tricyclic Antidepressants - 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.

Carmen Bergelin
Operations Specialist, Regulatory Affairs

San Diego, California, USA
Date: 23 Apr 2021

Appendix 1 to DOC # TF-1629		
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/AC:2016
Risk	Medical Devices – Application of risk management to medical devices	EN ISO 14971:2019
	Medical Devices – Application of usability engineering to medical devices	EN 62366:2015
Labeling	Symbols for use in the labeling of medical devices	EN 15223-1:2016
	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

9975 Summers Ridge Road, San Diego, CA 92121 USA | 1-877-441-7440 | www.abbott.com/poct