



DECLARATION OF CONFORMITY

DoC#: TF-1632, Rev 07.1

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)

Catalog Number	Device Description
DOA-124-441	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-134-101	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-134-141	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-144-021	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-144-031	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-144-051	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-144-841	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-144-1121	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-154-021	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-154-051	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-154-111	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-154-233	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-154-381	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-154-421	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-154-751	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-154-801	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-154-1031	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-154-1641	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-154-1661	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-154-1711	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA_154-2081	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-164-011	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-164-041	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-164-081	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-164-111	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-164-251	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-164-371	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-164-412	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-164-462	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-164-1401	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-164-1471	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-164-1641	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-164-2031	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-174-641	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-174-801	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)



Catalog Number	Device Description
DOA-174-951	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-184-263	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-184-671	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-194-311	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-194-351	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-011	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-031	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-132	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-222	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-241	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-291	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-341	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-611	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-621	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-961	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-1071	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-1171	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1104-1391	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1114-071	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1124-071	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1124-131	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DOA-1124-171	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DUD-184-431	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DUD-1104-561	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DUE-154-112	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DUE-174-641	SureStep™ Multi-Drug One Step Screen Test Panel (Urine)
DAM-114	SureStep™ Urine Drug Test Dip Card
DAM-A114	SureStep™ Urine Drug Test Dip Card
DBA-114	SureStep™ Urine Drug Test Dip Card
DBU-114	SureStep™ Urine Drug Test Dip Card
DBZ-114	SureStep™ Urine Drug Test Dip Card
DCO-114	SureStep™ Urine Drug Test Dip Card
DED-A114	SureStep™ Urine Drug Test Dip Card
DKE-114	SureStep™ Urine Drug Test Dip Card
DMD-114	SureStep™ Urine Drug Test Dip Card
DME-114	SureStep™ Urine Drug Test Dip Card
DMO-114	SureStep™ Urine Drug Test Dip Card
DMT-114	SureStep™ Urine Drug Test Dip Card
DOP-114	SureStep™ Urine Drug Test Dip Card
DTH-114	SureStep™ Urine Drug Test Dip Card
DTR-114	SureStep™ Urine Drug Test Dip Card
DOA-124-061	SureStep™ Urine Drug Test Dip Card
DOA-124-161	SureStep™ Urine Drug Test Dip Card
DOA-124-171	SureStep™ Urine Drug Test Dip Card



Abbott

Catalog Number	Device Description
DOA-124-421	SureStep™ Urine Drug Test Dip Card
DOA-134-291	SureStep™ Urine Drug Test Dip Card
DOA-134-631	SureStep™ Urine Drug Test Dip Card
DOA-134-751	SureStep™ Urine Drug Test Dip Card
DOA-144-081	SureStep™ Urine Drug Test Dip Card
DOA-144-171	SureStep™ Urine Drug Test Dip Card
DOA-144-601	SureStep™ Urine Drug Test Dip Card
DOA-154-201	SureStep™ Urine Drug Test Dip Card
DOA-154-301	SureStep™ Urine Drug Test Dip Card
DOA-154-381	SureStep™ Urine Drug Test Dip Card
DOA-154-421	SureStep™ Urine Drug Test Dip Card
DOA-154-501	SureStep™ Urine Drug Test Dip Card
DOA-154-721	SureStep™ Urine Drug Test Dip Card
DOA-154-731	SureStep™ Urine Drug Test Dip Card
DOA-154-1191	SureStep™ Urine Drug Test Dip Card
DOA-154-1431	SureStep™ Urine Drug Test Dip Card
DOA-154-1451	SureStep™ Urine Drug Test Dip Card
DOA-164-041	SureStep™ Urine Drug Test Dip Card
DOA-164-111	SureStep™ Urine Drug Test Dip Card
DOA-164-441	SureStep™ Urine Drug Test Dip Card
DOA-164-131	SureStep™ Urine Drug Test Dip Card
DOA-164-141	SureStep™ Urine Drug Test Dip Card
DOA-164-412	SureStep™ Urine Drug Test Dip Card
DOA-164-421	SureStep™ Urine Drug Test Dip Card
DOA-164-491	SureStep™ Urine Drug Test Dip Card
DOA-164-1401	SureStep™ Urine Drug Test Dip Card
DOA-164-1451	SureStep™ Urine Drug Test Dip Card
DOA-164-1621	SureStep™ Urine Drug Test Dip Card
DOA-164-1641	SureStep™ Urine Drug Test Dip Card
DOA-164-1771	SureStep™ Urine Drug Test Dip Card
DOA-164-1931	SureStep™ Urine Drug Test Dip Card
DOA-174-232	SureStep™ Urine Drug Test Dip Card
DOA-174-531	SureStep™ Urine Drug Test Dip Card
DOA-174-681	SureStep™ Urine Drug Test Dip Card
DOA-174-781	SureStep™ Urine Drug Test Dip Card
DOA-184-213	SureStep™ Urine Drug Test Dip Card
DOA-184-721	SureStep™ Urine Drug Test Dip Card
DOA-194-181	SureStep™ Urine Drug Test Dip Card
DOA-1104-011	SureStep™ Urine Drug Test Dip Card
DOA-1104-031	SureStep™ Urine Drug Test Dip Card
DOA-1104-051	SureStep™ Urine Drug Test Dip Card
DOA-1104-132	SureStep™ Urine Drug Test Dip Card
DOA-1104-161	SureStep™ Urine Drug Test Dip Card



Catalog Number	Device Description
DOA-1104-201	SureStep™ Urine Drug Test Dip Card
DOA-1104-481	SureStep™ Urine Drug Test Dip Card
DOA-1104-721	SureStep™ Urine Drug Test Dip Card
DOA-1104-981	SureStep™ Urine Drug Test Dip Card
DOA-1114-171	SureStep™ Urine Drug Test Dip Card
DOA-1124-031	SureStep™ Urine Drug Test Dip Card
DUD-164-043	SureStep™ Urine Drug Test Dip Card
DUD-1104-1291	SureStep™ Urine Drug Test Dip Card
DUE-154-1561	SureStep™ Urine Drug Test Dip Card
DUE-154-1761	SureStep™ Urine Drug Test Dip Card
DUE-164-1301	SureStep™ Urine Drug Test Dip Card
DUE-164-1282	SureStep™ Urine Drug Test Dip Card
DUE-164-1941	SureStep™ Urine Drug Test Dip Card
DUE-174-601	SureStep™ Urine Drug Test Dip Card
DUE-184-771	SureStep™ Urine Drug Test Dip Card
DUE-1104-711	SureStep™ Urine Drug Test Dip Card
DUE-1104-781	SureStep™ Urine Drug Test Dip Card
DUE-1104-941	SureStep™ Urine Drug Test Dip Card
DUE-1104-1301	SureStep™ Urine Drug Test Dip Card
DUE-1114-211	SureStep™ Urine Drug Test Dip Card

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: 12.70.09.70.00 – Multiple Drugs of Abuse – Toxicology
 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-1632		
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