



## DECLARATION OF CONFORMITY

DoC#: TF-1604, Rev 02.1

**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)**

FHC-102	SureStep ® hCG One Step Pregnancy Test Device (Urine)
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**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 60149668 0001, valid until 2021-08-24

Conformity Pathway: Annex III

Classification: Article 9, Section 1, Other IVD

EDMA Code: 12.70.05.02.00 – hCG 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: 12JUN2020



**Abbott**

<b>Appendix 1 to DOC # TF-1604</b>		
<b>Applicable Standards and Guidelines</b>		
<b>Category</b>	<b>Name</b>	<b>Number: Date Issued</b>
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
Risk	Medical Devices – Application of risk management to medical devices	EN ISO 14971:2019
	Elimination or reduction of risk of infection related to in vitro diagnostic medical devices	EN 13641:2002
Labeling	Symbols for use in the labeling of medical devices	EN ISO 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