InTec PRODUCTS, INC.

DECLARATION OF CONFORMITY

Manufacturer	**InTec PRODUCTS, INC.** 332 Xinguang Road, Xinyang Industrial Area. Haicang, Xiamen, P. R. China 361022
Authorized Representative	**Qarad b.v.b.a** Cipalstraat 3, B-2440 Geel, Belgium
Product Name	One Step Anti-HIV (1&2) Test
Product Code	ITPW02152-TC25, ITPW02152-TC40, ITPW02153-TC40
CE Certificate	V10605780020 Rev.02 (valid until 2024-05-26)
Classification:	List A
Notified Body:	(NB 0123) TÜV SÜD Product Service GmbH TÜV SÜD Gruppe - Zertifizierstelle Ridlerstr. 65 – 80339 München Germany

Standards applied:

No.	Reference	Title of Harmonized Standard
01	EN ISO 13485: 2016	Medical device-Quality management systems-Requirements for regulatory purposes
02	EN ISO 14971:2012	Medical device-Application of risk management to medical devices
03	EN ISO 15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
04	EN 13612:2002	Performance evaluation of *in vitro* diagnostic medical devices
05	EN ISO 18113-1:2011	Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
06	EN ISO 18113-2:2011	Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
07	EN ISO 23640: 2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
08	EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
09	2009/886/EC	Common Technical Specifications for In Vitro Diagnostic Medical Devices
10	EN 62366:2008	Medical devices-Application of usability engineering to medical devices
11	REGULATION (EC) No 1272/2008	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
12*	EN ISO 11137-1:2015	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
13*	EN ISO 11137-2:2015	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
* Only applicable to accessory sterile disposable safety lancets; only ITPW02153-TC40 contains sterile disposable safety lancets.		

Add: 332 Xinguang Road, Xinyang Industry Area, Haicang
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Nicole Zhang

Date: January 12, 2021
Nicole Zhang (Authorized Signatory)
Quality Director
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