



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4)
(List A)

No. V7 17 05 60578 017

Manufacturer: **InTec PRODUCTS, INC.**
332 Xinguang Road
Xinyang Industrial Area, Haicang
361022 Xiamen, Fujian
PEOPLE'S REPUBLIC OF CHINA



EC-Representative: **Qarad b.v.b.a**
Cipalstraat 3
B-2440 GEEL
BELGIUM

Product: **Reagents for determination of infection markers
for HIV-1/ HIV-2: Anti-HIV-1/ HIV-2 Rapid Tests**

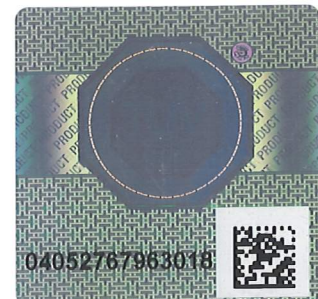
The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. See also notes overleaf.

Report No.: 713080459

Valid from: 2017-11-13
Valid until: 2022-11-12

Date, 2017-11-13

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



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No. V7 17 05 60578 017

Model(s): ONE STEP Anti-HIV (1&2) Test

Parameters: **Model Name:**
ONE STEP Anti-HIV (1&2) Test

Model No.:
ITP02152-TC40, ITP02152-TC25,
ITP02153-TC40, ITP02153-TC10

Facility(ies): InTec PRODUCTS, INC.
332 Xinguang Road, Xinyang Industrial Area,
Haicang, 361022 Xiamen, Fujian, PEOPLE'S
REPUBLIC OF CHINA

InTec PRODUCTS, INC.
308-8 Wengjiao Road, Xinyang Industrial Area,
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CHINA

Design Facility(ies): InTec PRODUCTS, INC.
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