

## CERTIFICATE OF COMPLIANCE

Applicant: Huayi Isotopes Co.  
Address of Applicant: 18Fuyu road, Changshu City, Jiangsu Province, China  
Manufacturer: Same as applicant  
Product Name: Reagents kits, O-18 water, Mannose Triflate, Sterile vial, cassettes and accessories  
Model No.: RK-210, WT-98, SV-10, Kt-110, As-200, KT-500, AS-100, RK-100.  
Intend use: Used for production of PET tracers  
Test report(s): TIJS1512186825  
Date of Issue: December 31th, 2015  
Date of Expire: December 31th, 2018

The submitted sample of the above product has been tested according to the following standard(s): **98/79/EC IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDD)**

**BS EN 13640 : 2002**

### Conclusion

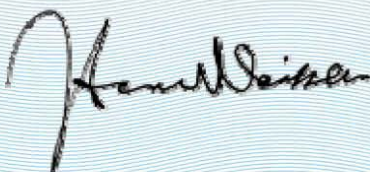
The referred test report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements.

The CE marking as shown below can be affixed on the product after preparation of necessary technical documentation.

Other relevant Directives have to be observed.

Approved by: Hermann Weiher

For and on behalf of  
Global Testing Services Co., Ltd



Global Testing Services Co., Ltd  
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