



CERTIFICATE

of Factory Production Control

Certificate no. 9794

HUAYI ISOTOPES CO.

18 Fuyu Road

Haiyu Town, Changshu City

Jiangsu Province, China 215522

Application of Council Directive 93/42/EEC.

This is to certify that the technical documentation for the following products complies with the requirements applicable to it. The manufacturer's Factory Production Control and technical documentation has been reviewed and found to comply EN 1041:2008;

EN ISO 15223-1:2012 and EN ISO 14971:2007

The application of the CE mark is permitted after all applicable requirements are met in accordance with The European Union rules.

**Reagents kits for PET and their accessories,
like Sterile vial, Cassettes, IFP and cartridges**

During the validity of this certificate, the requirements of the above mentioned regulations must be fulfilled permanently. This is supervised by QS Zürich AG.

For precise and updated information concerning possible changes occurred in the certification object of the present certificate, please contact info@@quality-service.cn



Audit date: 03.07.2013

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Expiration date: 02.07.2016

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