

GMP CERTIFICATE

This is to verify that the quality management system of:

Huayi Isotopes Co. a division of Jiangsu Huayi Technology Co., Ltd.

Registered Address: Fluorin Chemistry Industrial Park, Changshu Economic Technological Development Zone, Changshu City, Suzhou City, Jiangsu Province, China

Manufacturing address: No.18, Fuyu Road, Advanced Material Park, Haiyu Town, Changshu City, Suzhou City, Jiangsu Province, China

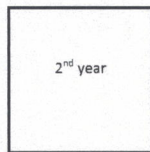
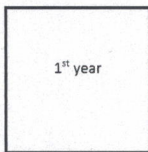
has been assessed by Intertek as conforming to the requirements of:

CURRENT GOOD MANUFACTURING PRACTICE BASED ON 21 CFR PART 210&211 (2020) PUBLISHED BY U.S. FOOD AND DRUG ADMINISTRATION

The scope of activities:

Manufacturing of Reagents kits for P.E.T., MX Cassette, IFP (Synthera Integrated Fluidic Processor TM), Sterile Vial, Oxygen-18 enriched Water, Mannose Triflate, 18F-FDG and PET Precursor (DOTA-TATE, DOTA-NOC, DOTA-TOC, PSMA-11, PSMA I&T, HDT, MDP)

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This certificate is valid as long as it bears a proper and authentic Intertek's Laser Logo dedicated for the year of initial audit and after satisfactory annual surveillance.



Certificate Number:

SZ2408F6

Initial Audit Date:

21-22 Sep, 2015

Issue Date:

27 Aug, 2024

Expiry Date:

22 Oct, 2027

Certification Administration Centre
Intertek Testing Services



Roger Huang
General Manager
HBP Audit

