PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE REGISTRATION CERTIFICATE

(English Translation for Reference)

Registration Certificate No.: 赣械注准 20242010142 (Jiangxi Province, China)

Issuing Authority: Jiangxi Provincial Drug Administration (江西省药品监督管理局)

Field	Information
Certificate Number	赣械注准 20242010142
Registrant	Jiangxi Xuchuang Medical Technology Co., Ltd. (江西续创医学科技有限公司)
Registrant Address	Plot 1-12-1-1, Lutian Industrial Park, Poyang County, Shangrao City, Jiangxi Province, China
Production Address	Plot 1-12-1-1, Lutian Industrial Park, Poyang County, Shangrao City, Jiangxi Province, China
Agent	Not applicable
Agent Address	Not applicable
Product Name	Disposable Radio Frequency Ablation Electrode (一次性使用射频消融电极)
Models / Specifications	See attached table (附表) — table not included in the source PDF provided for translation; refer to the product technical requirements.
Structure & Composition	The product consists of two parts: (1) an ablation electrode comprising the electrode, sheath, handle, water box, aviation connector, Luer connector, water tube and cable; and (2) a circulation water tube comprising a Luer connector, water tube, peristaltic tube, regulator and bottle-inserting needle. The product is sterile, sterilized by ethylene oxide, and intended for single use only.
Intended Use	For use in conjunction with radio-frequency (RF) high-frequency surgical equipment operating at 200 kHz – 750 kHz. Indicated for ablation and coagulation of tissues during non-endoscopic surgical procedures involving the liver, lung, kidney, gallbladder, spleen, thyroid, breast, prostate, uterine appendages, and lower-extremity venous tissues.
Attachments	Product Technical Requirements
Other Content	Not provided
Remarks	Not provided

Approval Authority	Jiangxi Provincial Drug Administration
Approval Date	9 July 2024
Effective Date	9 July 2024
Valid Until	8 July 2029

Notes

- The original certificate was issued by the Jiangxi Provincial Drug Administration (江西省药品监督管理局) and is presented in electronic form (https://mpa.jiangxi.gov.cn).
- This is a provincial-level (Class II) medical device registration in China. The product must be used together with compatible RF high-frequency surgical equipment, which is regulated under a separate registration.
- The attached model specification table (附表) was not included in the source PDF provided for translation. Please refer to the original certificate and the product technical requirements for the complete model list and dimensions.

Disclaimer: This document is an unofficial English translation of the corresponding People's Republic of China Medical Device Registration Certificate. The original Chinese version is the legally binding document. In case of any inconsistency, the Chinese original shall prevail. This translation is provided for international business and regulatory reference only.