PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE REGISTRATION CERTIFICATE

(English Translation for Reference)

Registration Certificate No.: 国械注准 20253010071 (NMPA China)

Issuing Authority: National Medical Products Administration (NMPA), People's Republic of China

Field	Information
Certificate Number	国械注准 20253010071
Registrant	Nanjing Lange Medical Technology Co., Ltd. (南京朗格医学科技有限公司)
Registrant Address	Rooms 231, 232, 233, Building 7, No. 8 Longtai Road, Jiangbei New Area, Nanjing, China
Production Address	Building 4, Phase I, Suzhou Life and Health Town Industrial Park, 1st–2nd Floor (Contract Manufacturing)
Product Name	Disposable Microwave Ablation Needle
Models / Specifications	See Appendix — Model Specification Matrix
Structure & Composition	The product consists of a needle tip, needle shaft, microwave cable, microwave connector, inlet/outlet water tubes and a handle. Certain models (B-series) additionally include an output cable.
Intended Use	For use in medical institutions in conjunction with the manufacturer's microwave ablation generators (models LG-MWS-10A, LG-MWS-10B, LG-MWS-10C, LG-MWS-11A, LG-MWS-11B and LG-MWS-11C, software release version V1) for the ablation of liver solid tumors or thyroid benign nodules. Refer to the product technical requirements for details.
Contract Manufacturer (Entrusted Production)	Dongmai Medical Technology (Suzhou) Co., Ltd. (东劢医疗科技（苏州）有限公司); Unified Social Credit Code: 91320505MA20FF9860
Approval Date	10 January 2025
Effective Date	10 January 2025
Valid Until	9 January 2030
Attachments	Product Technical Requirements; Model Specification Table

Appendix — Disposable Microwave Ablation Needle: Model Specification Matrix

No.	Model	Handle	Tip L1 (mm)	Tip Ø Φ1 (mm)	Shaft L2 (mm)	Shaft Ø Φ2 (mm)	Output Cable	Positioning Rings	Max Power (W)	Frequency (MHz)
1	LG-MWA-01A	Straight	12 ± 2	1.9 ± 0.5	200 ± 50	1.9 ± 0.5	Not included	1	70	2450 ± 50
2	LG-MWB-02A	Curved	12 ± 2	1.9 ± 0.5	200 ± 50	1.9 ± 0.5	Not included	1	70	2450 ± 50
3	LG-MWA-03A	Straight	7 ± 2	1.6 ± 0.2	130 ± 30	1.6 ± 0.2	Not included	1	50	2450 ± 50
4	LG-MWB-04A	Curved	12 ± 2	1.9 ± 0.5	130 ± 30	1.9 ± 0.5	Not included	1	70	2450 ± 50
5	LG-MWA-05A	Straight	7 ± 2	1.9 ± 0.5	170 ± 30	1.9 ± 0.5	Not included	1	70	2450 ± 50
6	LG-MWB-06A	Curved	7 ± 2	1.9 ± 0.5	170 ± 30	1.9 ± 0.5	Not included	1	70	2450 ± 50
7	LG-MWA-01B	Straight	12 ± 2	1.9 ± 0.5	200 ± 50	1.9 ± 0.5	Included	1	70	2450 ± 50
8	LG-MWB-02B	Curved	12 ± 2	1.9 ± 0.5	200 ± 50	1.9 ± 0.5	Included	1	70	2450 ± 50
9	LG-MWA-03B	Straight	7 ± 2	1.6 ± 0.2	130 ± 30	1.6 ± 0.2	Included	1	50	2450 ± 50
10	LG-MWB-04B	Curved	12 ± 2	1.9 ± 0.5	130 ± 30	1.9 ± 0.5	Included	1	70	2450 ± 50
11	LG-MWA-05B	Straight	7 ± 2	1.9 ± 0.5	170 ± 30	1.9 ± 0.5	Included	1	70	2450 ± 50
12	LG-MWB-06B	Curved	7 ± 2	1.9 ± 0.5	170 ± 30	1.9 ± 0.5	Included	1	70	2450 ± 50
13	LG-MWA-01D	Straight	12 ± 2	1.9 ± 0.5	200 ± 50	1.9 ± 0.5	Not included	2	70	2450 ± 50
14	LG-MWB-02D	Curved	12 ± 2	1.9 ± 0.5	200 ± 50	1.9 ± 0.5	Not included	2	70	2450 ± 50
15	LG-MWA-03D	Straight	7 ± 2	1.6 ± 0.2	130 ± 30	1.6 ± 0.2	Not included	2	50	2450 ± 50

16	LG-MWB-04D	Curved	12 ± 2	1.9 ± 0.5	130 ± 30	1.9 ± 0.5	Not included	2	70	2450 ± 50
17	LG-MWA-05D	Straight	7 ± 2	1.9 ± 0.5	170 ± 30	1.9 ± 0.5	Not included	2	70	2450 ± 50
18	LG-MWB-06D	Curved	7 ± 2	1.9 ± 0.5	170 ± 30	1.9 ± 0.5	Not included	2	70	2450 ± 50

Notes

- The original certificate was issued by the National Medical Products Administration (NMPA) of the People's Republic of China and is presented in electronic form (https://zwfw.nmpa.gov.cn).
- The disposable microwave ablation needle is a Class III medical device in China. It must be used together with the matched microwave ablation generator (see registration certificate 国械注准 20253010197).
- All dimensions in the appendix are expressed in millimetres (mm). Operating frequency 2450 ± 50 MHz.

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.