



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 406050 Device Technologies Australia Pty Ltd - External lesion localization marker, reusable

**ARTG entry for** Medical Device Included Class 1  
**Sponsor** Device Technologies Australia Pty Ltd  
**Postal Address** Locked Bag 521, FRENCHS FOREST, NSW, 2086  
Australia  
**ARTG Start Date** 10/03/2023  
**Product Category** Medical Device Class 1  
**Status** Active  
**Approval Area** Medical Devices

### Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.  
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Manufacturers

Name	Address
7D Surgical ULC	60 Scarsdale Road Unit 118 Toronto, ON, M3B 2R7 Canada

### Products

#### 1 . External lesion localization marker, reusable

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	10/03/2023
<b>GMDN</b>	47019 External lesion localization marker, reusable		
<b>Intended Purpose</b>	A reusable, external marker intended for the location and positioning of instruments and implants during a stereotaxic procedure.		

### Specific Conditions

No Specific Conditions included on Record

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