



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	341101	DermaSensor Pty Ltd - DermaSensor - Dermatological elastic scattering spectroscopy probe
<b>ARTG entry for</b>	Medical Device Included Class 1	
<b>Sponsor</b>	DermaSensor Pty Ltd	
<b>Postal Address</b>	58 Gipps Street, Collingwood, VIC, 3066 Australia	
<b>ARTG Start Date</b>	7/08/2020	
<b>Product Category</b>	Medical Device Class 1	
<b>Status</b>	Active	
<b>Approval Area</b>	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
DermaSensor Inc	80 SW 8th Street Suite 2000 Miami, Florida, 33130 United States Of America

### Products

#### 1 . DermaSensor - Dermatological elastic scattering spectroscopy probe

<b>Product Type</b>	Medical device system	<b>Effective Date</b>	7/08/2020
<b>GMDN</b>	64023 Dermatological elastic scattering spectroscopy probe		
<b>Intended Purpose</b>	The DermaSensor device is indicated for use as an objective tool to assist qualified healthcare professionals in evaluating skin lesions suggestive of melanoma, basal cell carcinoma, and/or squamous cell carcinoma. The DermaSensor device is intended to assist the user in deciding whether skin lesions require further clinical care and is not intended to be used for direct diagnosis of skin cancer. DermaSensor is only for use by qualified healthcare professionals appropriately trained in the assessment of skin lesions for cancer.		

### Specific Conditions

No Specific Conditions included on Record

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