



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	384586	Lenexa Medical Pty Ltd - Lenexa Medical Pressure Injury Management System (LEN200) - Pressure measurement/mapping system, anatomical
ARTG entry for	Medical Device Included Class 1	
Sponsor	Lenexa Medical Pty Ltd	
Postal Address	14 Kaleno View, Balwyn, VIC, 3103 Australia	
ARTG Start Date	23/02/2022	
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
Lenexa Medical Pty Ltd	14 Kaleno View Balwyn, VIC, 3103 Australia

Products

1 . Lenexa Medical Pressure Injury Management System (LEN200) - Pressure measurement/mapping system, anatomical

Product Type	Medical device system	Effective Date	23/02/2022
GMDN	43829 Pressure measurement/mapping system, anatomical		
Intended Purpose	The LEN200 shall be used by clinicians and carers to provide information with respect to what position the patient is resting in and for how long they have been in such positions.		

Specific Conditions

No Specific Conditions included on Record

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