



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	320851	Gamma Gurus Pty Ltd - Patient positioning device, diagnostic imaging/radiotherapy, moulding system, foam
ARTG entry for	Medical Device Included Class 1	
Sponsor	Gamma Gurus Pty Ltd	
Postal Address	PO Box 211, Engadine, NSW, 2233 Australia	
ARTG Start Date	26/07/2019	
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
ESSEBI MEDICAL Srl	Strada Campo Del Fiume 84 , Faetano, 47896 San Marino

Products

1. Patient positioning device, diagnostic imaging/radiotherapy, moulding system, foam

Product Type	Single Device Product	Effective date	26/07/2019
GMDN	40894 Patient positioning device, diagnostic imaging/radiotherapy, moulding system, foam		
Intended purpose	Expandable foam mouldable cushion that hardens to provide immobilisation and consistent patient positioning, through imaging, simulation and daily radiation therapy treatment.		

Specific Conditions

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