



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	299351	GAMA Healthcare Australia Pty Ltd - Medical device cleaning/disinfecting wipe
ARTG entry for	Medical Device Included Class IIb	
Sponsor	GAMA Healthcare Australia Pty Ltd	
Postal Address	1/395 Nepean Highway, Frankston, VIC, 3199 Australia	
ARTG Start Date	6/02/2018	
Product Category	Medical Device Class IIb	
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
Gama Healthcare Ltd	2 Regal Way , Watford, WD24 4YJ United Kingdom

Products

1 . Medical device cleaning/disinfecting wipe

Product Type	Single Device Product	Effective Date	6/02/2018
GMDN	58077 Medical device cleaning/disinfecting wipe		
Intended Purpose	Low level Instrument Grade Disinfectant with wide spectrum antimicrobial activity including MRSA and VRE, Acinetobacter (DR) and Klebsiella (CRE), virucidal activity against SARS-CoV-2 (COVID-19), Norovirus, Influenza (H1N1) and fungicidal activity. Effective on surfaces.		

Specific Conditions

No Specific Conditions included on Record

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