

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

GAMA Healthcare Australia Pty Ltd - Clinell Universal Sanitizing Wipes and Spray - Disinfectant, hospital grade - Specific claims - "Benzalkonium chloride, Didecyldimethylammonium chloride, "PHMB" Summary for ARTG Entry: 178363

ARTG entry for Other Therapeutic Good - Listed disinfectant

GAMA Healthcare Australia Ptv Ltd Sponsor

Postal Address 1/395 Nepean Highway, Frankston, VIC, 3199

Australia

ARTG Start Date 14/12/2010

Product Category Other Therapeutic Good

Medical Devices Approval Area

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

- 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

Products

1 . Clinell Universal Sanitising Wipes

19/03/2018 8:29:30 AM **Product Type Effective Date** Single Device Product

GMDN 9950 Disinfectant, hospital grade

Intended Purpose Hospital Grade Disinfectant with wide spectrum bactericidal activity including MRSA and VRE. Effective against Coronavirus

including COVID-19. Hard surface disinfectant only. Not to be used on medical devices or other therapeutic goods. Not to be used

on skin

Specific Conditions

No Specific Conditions included on Record

2. Clinell Universal Hospital Grade Disinfectant Spray

Product Type Effective Date 6/08/2018 4:39:51 PM Single Device Product

GMDN 9950 Disinfectant, hospital grade

Intended Purpose Hospital Grade Disinfectant with wide spectrum bactericidal activity including MRSA and VRE. Effective against Coronavirus

including COVID-19. Hard surface disinfectant only. Not to be used on medical devices or other therapeutic goods. Not to be used

on skin

Specific Conditions

No Specific Conditions included on Record

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