

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: Microsafe Care Australia Pty Ltd - Nanocyn Disinfectant & Sanitiser with Specific Claims - Disinfectant, 292455

hospital grade

Other Therapeutic Good - Registered disinfectant ARTG entry for

Microsafe Care Australia Ptv Ltd Sponsor

Postal Address 150 Williams Road, Mount Duneed, VIC, 3216

Australia

ARTG Start Date 5/08/2017

Product Category Other Therapeutic Good

Medical Devices Approval Area

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995

Products

1 . Nanocyn Disinfectant & Sanitiser with Specific Claims - Disinfectant, hospital grade

Effective Date 9/08/2017 12:35:28 PM Product Type Single Device Product

GMDN 9950 Disinfectant, hospital grade

Intended Purpose The Nanocyn Disinfectant & Sanitiser is a hospital grade, hard surface disinfectant effective against: Bacteria - including

Staphylococcus aureus (MRSA), E. coli, Pseudomonas aeruginosa, Fungi & Mold - including Candida Albicans, (30 seconds contact time), T. mentagrophyte (Tinea). Viruses - including Herpes Simplex, Norovirus (Gastro), Influenza A (H1N1) and Coronavirus including SARS-COV-2 (COVID-19), in 15 seconds. Nanocyn Disinfectant & Sanitiser is intended for use in medical, dental, healthcare, aged care, aviation, transport, educational, public, leisure, office, food producing and general environments. Intended to be used in quarantine facilities including hotel quarantine. The product can be applied with a misting, fogging, ULV and electrostatic delivery devices. Not intended for use on medical devices or other therapeutic goods. Not to be used on skin.

Specific Conditions

For the hard surface disinfectants that are retained on the part of the ARTG for registered goods,

you, as sponsor, are required to comply with the standard and specific conditions for registered

goods in Appendix 4, Standard Conditions applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989 of DR4 applied at the time of registration and is ongoing.

Pursuant to Section 28(2B) of the Therapeutic Goods Act 1989, I have decided to impose "The

listing number must be placed on the label of the device by writing the number, immediately preceded by "AUST R" so that it is clearly visible to the user on (i) the label of the device; or (ii) the label on the outermost level of packaging in which the device is to be supplied to the user

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