Public Summary

Summary for ARTG Entry: 165058 Diversey Australia Pty Limited - Oxivir Tb, Hospital Grade Disinfectant with claims, Non-Sterile

ARTG entry for	Other Therapeutic Good Registered
Sponsor	Diversey Australia Pty Ltd
Postal Address	29 Chifley Street, SMITHFIELD, NSW, 2164 Australia
ARTG Start Date	8/09/2009
Product category	Other Therapeutic Good
Status	Active
Approval area	Medical Devices

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. Oxivir Tb - Disinfectant, hospital grade with claims

Product Type Single Device Product **Effective date** 8/09/2009

GMDN	9950 Disinfectant, hospital grade
Intended purpose	Oxivir Tb is a one step disinfectant, cleaner and odour neutraliser. It requires no post use rinsing when used on non-food contact surfaces. It will clean and disinfect most surfaces found in health, educational and recreational environments. Oxivir Tb is highly effective against a wide variety of pathogenic microorganisms including bacteria, antibiotic resistant bacteria, viruses such as SARS-CoV-2 (COVID-19 virus) and fungi. Hard surface disinfectant only. Not to be used on skin. Not intended to be used on medical devices or other therapeutic goods.

Specific Conditions

Standard 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.
AUST R
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

Acceptable data has been provided to support a 36 month shelf life.

This product is approved with an 18 month shelf life stored below 25 degree Celsius. Batches of product must be tested during and at the end of the closed shelf life period. End of shelf life period testing must be generated from the most stringest test, in this case Mycobacterium.