Public Summary

Summary for ARTG Entry:	343050	Novapharm Research (Australia) Pty Ltd - Benzalkonium Chloride - With Specific Claims - Disinfectant, hospital grade

ARTG entry for	Other Therapeutic Good - Listed disinfectant
Sponsor	Novapharm Research (Australia) Pty Ltd
Postal Address	PO Box 151, ROSEBERY NSW, NSW, 2018 Australia
ARTG Start Date	6/09/2020
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 . ABS Anti-Bacterial Sheets (Hard Surface Disinfectant Paper Wipe)

Product Type	Single Device Product	**Effective Date**	2/10/2020 2:54:21 PM
GMDN	9950 Disinfectant, hospital grade		
Intended Purpose	Hospital Grade Hard Surface Disinfecting Paper Wipes. For the cleaning & disinfection of surfaces including food preparation areas. Kills germs & bacteria. Effective against COVID-19 & Influenza H1N1 viruses. Activated when paper becomes wet. Not to be used on skin. Not to be used on medical devices and other therapeutic goods.		

Specific Conditions

1. Standards
The listed goods must comply with standards applicable to those goods under part 3 of the Act.

2. Changes to Goods
Changes to Goods Changes or variations in respect of any information concerning the listed therapeutic goods, being information that would have been relevant* to a decision to list the goods in the Register, including information on the formulation of the listed goods or other aspects of their manufacture, and the labelling of the goods, shall forthwith be notified to the Secretary, or the Secretary's delegate appointed for the purposes of section 28 of the Act, and where necessary*, the change or variation shall not be implemented until approved by the Secretary. (*Reference should also be made to the Guidance on the Regulation of Disinfectants in Australia).

3. Records Held
i. The sponsor of the listed goods shall keep such records relating to the goods as are necessary: (a) to expedite recall if necessary of any batch of the listed goods; (b) to identify the manufacturer(s) of each batch of the listed goods. Where any part of or step in the manufacture in Australia of the listed goods is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relating to such manufacture shall be kept.
ii. Each sponsor shall retain records of the distribution of all of the sponsor's listed goods for a period of five years and upon the request of the Therapeutic Goods Administration, shall provide the records or copies of the records.

4. Sampling
The sponsor of the listed goods shall permit officers who have been authorised under the Regulations to do so to take samples of therapeutic goods and carry out related duties in accordance with the Regulations.

5. Overseas Regulatory Actions
Where the listed goods are distributed regularly overseas as well as in Australia, product recall or any actions other similar regulatory action taken in relation to the goods outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia must be notified to the Therapeutic Goods Administration via Post Market Surveillance email, MedicalDeviceSurveillance@health.gov.au as soon as the action or information is known to the sponsor.

6. Indications
In relation to listed goods, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods and, upon the request of the Therapeutic Goods Administration, shall produce such evidence.

2 . Aeris Active Hard Surface Disinfecting Paper (Disinfectant Wipe)

Product Type	Single Device Product	**Effective Date**	2/10/2020 2:54:21 PM
GMDN	9950 Disinfectant, hospital grade		
Intended Purpose	Hospital Grade Hard Surface Disinfecting Paper Wipes. For the cleaning & disinfection of surfaces including food preparation areas. Kills germs & bacteria. Effective against COVID-19 & Influenza H1N1 viruses. Activated when paper becomes wet. Not to be used on skin. Not to be used on medical devices and other therapeutic goods.		

Specific Conditions

1. Standards
The listed goods must comply with standards applicable to those goods under part 3 of the Act.

2. Changes to Goods
Changes to Goods Changes or variations in respect of any information concerning the listed therapeutic goods, being information that would have been relevant* to a decision to list the goods in the Register, including information on the formulation of the listed goods or other aspects of their manufacture, and the labelling of the goods, shall forthwith be notified to the Secretary, or the Secretary's delegate appointed for the purposes of section 28 of the Act, and where necessary*, the change or variation shall not be implemented until approved by the Secretary. (*Reference should also be made to the Guidance on the Regulation of Disinfectants in Australia).

3. Records Held
i. The sponsor of the listed goods shall keep such records relating to the goods as are necessary: (a) to expedite recall if necessary of any batch of the listed goods; (b) to identify the manufacturer(s) of each batch of the listed goods. Where any part of or step in the manufacture in Australia of the listed goods is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relating to such manufacture shall be kept.
ii. Each sponsor shall retain records of the distribution of all of the sponsor's listed goods for a period of five years and upon the request of the Therapeutic Goods Administration, shall provide the records or copies of the records.

4. Sampling
The sponsor of the listed goods shall permit officers who have been authorised under the Regulations to do so to take samples of therapeutic goods and carry out related duties in accordance with the Regulations.

5. Overseas Regulatory Actions
Where the listed goods are distributed regularly overseas as well as in Australia, product recall or any actions other similar regulatory action taken in relation to the goods outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia must be notified to the Therapeutic Goods Administration via Post Market Surveillance email, MedicalDeviceSurveillance@health.gov.au as soon as the action or information is known to the sponsor.

6. Indications
In relation to listed goods, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods and, upon the request of the Therapeutic Goods Administration, shall produce such evidence.

3 . RapidClean ActivePaper

Product Type	Single Device Product	**Effective Date**	8/03/2021 9:10:15 AM
GMDN	9950 Disinfectant, hospital grade		
Intended Purpose	Hospital Grade Hard Surface Disinfecting Paper Wipes. For the cleaning & disinfection of surfaces including food preparation areas. Kills germs & bacteria. Effective against COVID-19 & Influenza H1N1 viruses. Activated when paper becomes wet. Not to be used on skin. Not to be used on medical devices and other therapeutic goods.		

Specific Conditions

1. Standards
The listed goods must comply with standards applicable to those goods under part 3 of the Act.

2. Changes to Goods
Changes to Goods Changes or variations in respect of any information concerning the listed therapeutic goods, being information that would have been relevant* to a decision to list the goods in the Register, including information on the formulation of the listed goods or other aspects of their manufacture, and the labelling of the goods, shall forthwith be notified to the Secretary, or the Secretary's delegate appointed for the purposes of section 28 of the Act, and where necessary*, the change or variation shall not be implemented until approved by the Secretary. (*Reference should also be made to the Guidance on the Regulation of Disinfectants in Australia).

3. Records Held
i. The sponsor of the listed goods shall keep such records relating to the goods as are necessary: (a) to expedite recall if necessary of any batch of the listed goods; (b) to identify the manufacturer(s) of each batch of the listed goods. Where any part of or step in the manufacture in Australia of the listed goods is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relating to such manufacture shall be kept.
ii. Each sponsor shall retain records of the distribution of all of the sponsor's listed goods for a period of five years and upon the request of the Therapeutic Goods Administration, shall provide the records or copies of the records.

4. Sampling
The sponsor of the listed goods shall permit officers who have been authorised under the Regulations to do so to take samples of therapeutic goods and carry out related duties in accordance with the Regulations.

5. Overseas Regulatory Actions
Where the listed goods are distributed regularly overseas as well as in Australia, product recall or any actions other similar regulatory action taken in relation to the goods outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia must be notified to the Therapeutic Goods Administration via Post Market Surveillance email, MedicalDeviceSurveillance@health.gov.au as soon as the action or information is known to the sponsor.

6. Indications
In relation to listed goods, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods and, upon the request of the Therapeutic Goods Administration, shall produce such evidence.