Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Novapharm Research (Australia) Pty Ltd

for approval to supply

NOVAPHARM NON STERILE DISINFECTANTS - WITH CLAIMS - (HYDROGEN PEROXIDE/ BENZALKONIUM CHLORIDE)

ARTG Identifier	331860
ARTG Start Date	20/03/2020
Product Category	Other Therapeutic Good Other Therapeutic Good - Listed disinfectant
Intended Purpose	Hard surface hospital grade disinfectant cleaner effective against a broad spectrum of Bacteria including MRSA and VRE, Fungi and Viruses including Covid-19 (Sars Cov-2), Norovirus, and influenza viruses. Residual antibacterial for up to 30 days or 200 touches against gram-negative E. coli and gram-positive S. aureus. Residual Covid-19 kill for up to 7 days. Kills Covid 19 in 1 minute. Not to be used on skin. Not to be used on medical devices or other therapeutic goods.

Manufacturer Details	Address	Certificate number(s)
Novapharm Research (Australia) Pty Ltd	3-11 Primrose Avenue ROSEBERY NSW , NSW , 2018 Australia	

ARTG Standard Conditions

The above Other Therapeutic Good Other Therapeutic Good - Listed disinfectant has been entered on the Register subject to the following 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 Covered by This Entry

1. Aeris Active & Evocide Extra Hospital Grade Disinfectant Cleaner - Disinfectant, hospital grade

Product 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 Devices 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 Hospital Grade Disinfectant Cleaner 5L

Product 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 Devices 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. Evocide Extra (PF-058) Hospital Grade Disinfectant Cleaner 500ml

Product 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 Devices 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.

4. Evocide Extra (PF-058) Hospital Grade Disinfectant Cleaner 1L

Product 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 Devices 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.

5. Aeris Active Hospital Grade Disinfectant Cleaner 750ml

Product 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 Devices 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.

6. Aeris Active Hospital Grade Disinfectant Cleaner 750ml Spray

Product 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 Devices 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.

7. Sabco Ultrashield Pro Hospital Grade Disinfectant - 500ml and 750ml

Product 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 Devices 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.
