



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

## Public Summary

<b>Summary for ARTG Entry:</b>	335971	Hydro-E Pty Ltd - Hydro-E Hospital Grade Disinfectant - Disinfectant, hospital grade
<b>ARTG entry for</b>	Other Therapeutic Good - Listed disinfectant	
<b>Sponsor</b>	Hydro-E Pty Ltd	
<b>Postal Address</b>	35 Weeroona Road, Lidcombe, NSW, 2141 Australia	
<b>ARTG Start Date</b>	7/05/2020	
<b>Product Category</b>	Other Therapeutic Good	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Hydro-E Hospital Grade Disinfectant - Disinfectant, hospital grade

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	7/05/2020
<b>GMDN</b>	9950 Disinfectant, hospital grade		
<b>Intended Purpose</b>	Hydro-E is a hard surface disinfectant which is effective against germs and a broad range of bacteria including staphylococcus aureus, Escherichia coli, Salmonella typhimurium and Pseudomonas aeruginosa. Kills SARS-CoV-2 (Covid-19). Not to be used on medical devices or 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 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.

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