

25<sup>th</sup> May 2026

**Product Correction**  
**TGA Reference Number: RC-2026-RN-00397-1**  
**Clinell Universal Wipes - Pack of 200, CW200AUS**

ARTG Number	299351					
Product Code	CW200AUS					
LOT (Batch) Numbers	UJK4104323A	UJK1104623A	UJK6105123A	UJK3101424A	UJK2101524A	UJK6102224A
	UJK5104323A	UJK2104623A	UJK1105223A	UJK5101424A	UJK3101524A	UJK1102324A
	UJK6104323A	UJK3104623A	UJK2105223A	UJK6101424A	UJK4102224A	
	UJK1104423A	UJK5105123A	UJK3105223A	UJK1101524A	UJK5102224A	

Dear Valued Customer,

GAMA Healthcare Australia Pty Ltd., following agreement with the Therapeutic Goods Administration (TGA), is conducting a Product Correction for the above product. The potentially affected product may have been supplied to your organisation.

### What is the problem?

A portion of Clinell Universal Wipes - Pack of 200 wipes distributed in Australia during January 2024 to March 2026, (but with 99% being supplied in 2024) included additional efficacy claims (Hepatitis B and Hepatitis C) on a small side section of the product packaging (please refer to Appendix I).

While these claims are factually supported by testing to recognised European (EN) standards, testing to specific TGA requirements for these claims has not been performed.

### Risk assessment:

- This problem relates to labelling presentation only and does not affect product formulation, quality, or core disinfectant performance.
- There is no impact on the product's intended use when used according to the Instructions for Use (IFU).
- The problem is unlikely to lead to harm.

Importantly:

- The primary efficacy table on pack does not include these additional claims (please refer to Appendix II).
- All supporting literature, IFU posters and education provided did not include these efficacy claims.
- The product remains compliant with its approved TGA-cleared claims.
- The product is CE marked and conforms to EU MDR requirements.

This action does not affect any other GAMA Healthcare products.

### What should you do?

- Please place the informational poster provided in visible locations around your organisation:  
<https://tinyurl.com/PCN-CW200>
- You may continue to use the product in accordance with existing cleaning and disinfection protocols, and in accordance with the efficacy table on the product labelling
- Please refer to the correct efficacy claims published on our website:  
<https://gamahealthcare.com.au/products/universal-range/>
- Please review the attached IFU efficacy poster, which provides:
  - Verified efficacy claims aligned with TGA requirements
  - Correct usage instructions
- Return the Customer Response Form, even if you do not have any affected product

GAMA Healthcare Australia Pty Ltd.,  
Suite 1, 33-37 Duerdin Street,  
Notting Hill, Victoria 3168, Australia

T +61 (0)3 9769 6600  
E [info@gamahealthcare.com.au](mailto:info@gamahealthcare.com.au)  
[gamahealthcare.com.au](http://gamahealthcare.com.au)



Please ensure this information is communicated to relevant staff.

If you have supplied this product to another facility, please forward this letter.

**What are we doing?**

We have:

- Initiated this market action in consultation with the TGA
- Reviewed all external materials (including website and IFU) to ensure alignment with approved claims
- Implemented internal controls to prevent inclusion of unreviewed claims on packaging in future.

Please contact GAMA Healthcare Australia at email: [ausquality@gamahealthcare.com.au](mailto:ausquality@gamahealthcare.com.au) or call 03 9769 6600, if any further clarification is required.

GAMA Healthcare sincerely regrets any inconvenience caused to your organisation.

Yours sincerely,

A handwritten signature in blue ink, consisting of a series of loops and a long, sweeping tail.

Suzie Hammouche  
CEO



## Appendix II

**Clinell Universal Wipes** act as a disinfectant and detergent wipe for non-invasive medical devices. They contain a patented formula with wide spectrum antimicrobial activity, including bactericidal activity against MRSA, VRE, *Klebsiella* (CRE) and *Acinetobacter*, and virucidal activity against Norovirus, Influenza (H1N1), Herpes Simplex Virus and Coronavirus. Clinell Universal Wipes provide a single universal product that cleans and disinfects in one easy step.

**CAUTION:** Avoid contact with eyes. Discontinue use if irritation develops. If irritation persists for more than 72 hours, seek medical advice. Do not use on complex or invasive medical devices. Always follow medical device manufacturer's cleaning and disinfection guidelines. Keep out of the reach of children. Store in a cool, dry, well ventilated area, away from direct sunlight. Keep pack closed when not in use. Leave the surface to air dry for a minimum of 1 minute.

BACTERIA	CONTACT TIME	TEST
<i>Pseudomonas aeruginosa</i>	60 seconds	EN 13727, EN 14561
<i>Enterococcus hirae</i>	60 seconds	EN 13727, EN 14561
<i>Enterococcus faecium</i> (VRE)	60 seconds	EN 13727, EN 14561
<i>Enterobacter cloacae</i> (CRE)	60 seconds	EN 14561
<i>Klebsiella pneumoniae</i> (CRE)	60 seconds	EN 13727, EN 14561
<i>Acinetobacter baumannii</i>	60 seconds	EN 13727, EN 14561
<i>Staphylococcus aureus</i> (MRSA)	60 seconds	EN 13727, EN 14561
<i>Staphylococcus aureus</i>	60 seconds	EN 13727, EN 14561
<b>YEAST</b>		
<i>Candida auris</i>	10 seconds	EN 13624
<b>VIRUSES</b>		
Norovirus (MNV surrogate)	60 seconds	EN 14476
Influenza (H1N1)	60 seconds	EN 14476 (modified)
Herpes Simplex Virus	60 seconds	ASTM E1053-11
SARS-CoV-2 (Coronavirus)	30 seconds	EN 14476
Adenovirus	60 seconds	EN 14476

WIPES  
 200

AT LEAST 99.99% KILL RATE, EFFECTIVE AGAINST MRSA, ACINETOBACTER, VRE, NOROVIRUS, HEPATITIS B & C AND MANY MORE.