



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

UPDATED CRITICAL QUARANTINE

UPDATE 28/03/25 - The continuing investigation has determined that the risk of contamination for most of the products is very low, and the quarantine can now be LIFTED for all product codes except RHS421 and RHS475.

LEVEL: Retail

CLASS: Class I

TGA REF: RC-2025-RN-00344-1

AGREEMENT DATE: 26/03/2025

PRODUCT: Reynard Adhesive Removal Wipes, Reynard Alcohol Prep Pads and Reynard Alcohol/Chlorhexidine Swabsticks

Multiple products and product codes

Batch numbers: All

ARTG's 309541, 309236 and 309237 (all cancelled)

SPONSOR: Reynard Health Supplies (Aus) Pty Ltd

REASON:

The TGA has received reports of potential Achromobacter contamination. It has been determined a likely source of contamination is materials and products associated with the manufacturer Baoying County Fukang Medical Appliance Co Ltd.

While the investigation is ongoing into the potential contamination of bacteria Achromobacter, it has not been determined if the above products are affected. However, out of an abundance of caution, products from this manufacturer are to be quarantined until further notice.

UPDATE 28/03/25 - Following additional Whole Genome Sequencing testing on recent positive cultures, the TGA has determined that the risk of contamination of these products is very low, and they may continue to be used. However the risk posed from product codes RHS421 and RHS475 is still being investigated, and they should remain in quarantine.

PROPOSED CUSTOMER

ACTIONS: Customers are to stop using these products and quarantine the affected stock on site until further notice.

This problem is still being investigated and updates will be provided when available.



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

UPDATE 28/03/25 - The continuing investigation has determined that the risk of contamination by most of the products is very low, and the quarantine can now be LIFTED for all product codes except RHS421 and RHS475.

It is recommended customers remove all other product codes impacted by this action (excluding RHS421 and RHS475) from quarantine immediately, and allow for their continued use.

SPONSOR

CONTACT

INFORMATION: 1300 667 199 - Reynard Health Supplies

Please note that this notification is provided pursuant to subsections 61(3) and 61(7) of the Therapeutic Goods Act 1989.