Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-01130-1
Product Name/Description[iii]	Gelflex Sterile Eye Wash Normal Saline 10mL Ampoule Product code: 8200 Batch number: 1T2324002 Expiry Date: December 2017 ARTG Number: 151536
Recall Action Level[iv]	Retail
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	7/11/2014
Responsible Entity[vii]	Covidien Pty Ltd
Reason / Issue[viii]	Covidien Pty Ltd (Covidien), following advice from the Therapeutic Goods Administration and the manufacturer Marck Biosciences Ltd (now known as Amanta Healthcare Ltd) that batch number 1T2324002 of the below product has failed the test for sterility, is recalling this batch at the retail level. Please note that there have been no adverse events reported regarding this sterility test failure.
Recall Action[ix]	Recall
Recall Action Instructions[x]	Covidien is requesting the customers to identify and quarantine the affected stock. Covidien will arrange for shipment pickup from the distribution centre and will provide credit note for the returned stock.
Contact Information[xi]	1800 252 467 - Covidien Customer Service

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.