

From: Recalls <Recalls@health.gov.au>
Sent: Monday, 19 November 2018 3:29 PM
Subject: Final letter to sponsor - RC-2017-RN-01125-1 [SEC=UNCLASSIFIED]
Attachments: Final letter to sponsor - RC-2017-RN-01125-1.pdf

Dear [REDACTED]

Please find attached the close out letter for the above recall action. This is now considered to be complete in accordance with the requirements of the Uniform Recall Procedure for Therapeutic Goods and has been finalised on the recalls database.

Kind Regards,

[REDACTED]
Recalls Section
Manufacturing Quality Branch

Phone: [REDACTED]
Fax: [REDACTED]
Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au


This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.



Australian Government
Department of Health
 Therapeutic Goods Administration

In reply please quote: RC-2017-RN-01125-1

Managing Director
 Australasian Medical & Scientific Ltd
 PO Box 5197

WEST CHATSWOOD NSW 1515

Attention: [REDACTED]
 Your reference:
 19/11/2018

Dear Sir/Madam,

Subject:
Essure Permanent Birth Control

Catalogue Number/Order Code: ESS305

All Batch Numbers

ARTG Number: 174123

Thank you for your final report regarding the recall action involving the above therapeutic good(s).

Copies of the close out reports have now been reviewed by the TGA's Recalls Section regarding the effectiveness of the recall action itself. This information will also be used as part of ongoing monitoring and compliance activities undertaken by the TGA.

This recall action is now considered to be completed in accordance with the requirements of the current Uniform Recall Procedure for Therapeutic Goods ([URPTG](#)) and has been closed on the recalls database.

As part of finalising this action, the TGA Recalls Section is requesting that Sponsors verify the staff contact details given in the TBS Portal are up to date as per the guidance given in this link: <https://www.tga.gov.au/tga-business-services-questions-and-answers-administrators>

Please do not hesitate to contact me on the numbers below if you have any further concerns on this issue.

Yours sincerely,

[REDACTED]
Recalls Section
Manufacturing Quality Branch

Phone: [REDACTED]
Email: Recalls@health.gov.au

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
www.tga.gov.au

[REDACTED]
(Signed electronically)