

**From:** [REDACTED]  
**To:** [REDACTED]  
**Subject:** RE: Essure System ARTG 174123 [SEC=UNCLASSIFIED]  
**Date:** Wednesday, 10 September 2014 12:17:33 PM

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Dear [REDACTED]

I have been asked by BAYER Australia to provide you with the statement below regarding the status of the CE Mark Suspension.

**Status update concerning the investigations of the Irish Notified Body**

The follow-up audit regarding the re-establishment of the ISO 13485/CMDCAS and CE Mark -certification took place on August 27 – 28, 2014.

The NSAI Lead Auditor's preliminary conclusion after the re-audit was: *"The audit team found that appropriate and effective changes have been made in response to the findings and that the suspension of the quality system certificate can be lifted."*

The Lead Auditor's preliminary feedback is subject to certain internal routine NSAI review and approval processes. A written and final confirmation regarding the re-establishment of ISO 13485/CMDCAS and CE Mark -certification might not be available before mid-end of September 2014.

Kind Regards

[REDACTED]  
Managing Director  
Gytech Pty Ltd

P: [REDACTED]  
F: [REDACTED]  
M: [REDACTED]  
E: [REDACTED]

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**From:** [REDACTED] [mailto:[REDACTED]]  
**Sent:** Monday, 11 August 2014 10:55 AM  
**To:** [REDACTED]  
**Subject:** Essure System ARTG 174123 [SEC=UNCLASSIFIED]

Dear [REDACTED]

Thank you for your response to my s41JA request for information. In your response you indicated that Bayer is in the process of responding to the notified body (NSAI) to address the audit findings and that Bayer is confident that the suspension will be a temporary matter. Based on the information you have provided and until the matter is resolved no further action is required by Gytech Pty Ltd.

Please provide details of the outcome of this matter as soon as they become available.

Regards

[REDACTED]  
Departmental Officer  
Device Vigilance and Monitoring  
Office of Product Review

Phone: [REDACTED] Fax: [REDACTED]  
Email: [REDACTED]

**Therapeutic Goods Administration**

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