**From:** [redacted]
**To:** [redacted]
**Subject:** FW: Essure - ARTG 174123 - Notification of CE Certificate suspension [SEC=UNCLASSIFIED]
**Date:** Friday, 25 July 2014 9:59:23 AM
**Attachments:** image001.png
TGA letter 23 July 2014.pdf

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Hi [redacted]

Please see attached information about the suspension of a QMS CE certificate.

The letter is a little short on details so could one of you please write to the sponsor today requesting more details. This should be done under s41JA so that we have base to begin with should regulatory action be required.

Thanks
[redacted]

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**From:** [redacted] **On Behalf Of** Recalls
**Sent:** Thursday, 24 July 2014 3:13 PM
**To:** Devices Verification Section; Devices; [redacted]
**Cc:** [redacted]
**Subject:** FW: Essure - ARTG 174123 - Notification of CE Certificate suspension [SEC=UNCLASSIFIED]

Good afternoon,

Please see attached.

Kind regards,

**Recalls**
TGA Recalls and Advertising
Office of Product Review

Phone: [redacted]
Fax: [redacted]
Email: recalls@tga.gov.au

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

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**From:** [redacted] **On Behalf Of** Devices
**Sent:** Wednesday, 23 July 2014 2:42 PM
**To:** Devices Verification Section; Recalls
**Subject:** FW: Essure - ARTG 174123 - Notification of CE Certificate suspension [SEC=UNCLASSIFIED]

Good afternoon DVS/Recalls

Please see the attached email that has been received by the devices information unit regarding a suspension of an ec certificate that may require your action or review.

It appears that the parties concerned are meeting the requirements that have been put in place however I am unsure if the TGA needs to take action or respondto such a notification.

Please advise if you are not the appropriate area for this.

Kind regards
[redacted]

**Medical Devices Information Unit**
Office of Devices Authorisation
Therapeutic Goods Administration
Phone: 1 800 141 144
Fax: [redacted]
Email: [redacted]

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

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**From:** [redacted]
**Sent:** Wednesday, 23 July 2014 12:35 PM
**To:** Devices
**Cc:** [redacted]
**Subject:** Essure - ARTG 174123 - Notification of CE Certificate suspension

Dear Office of Devices,

Please find attached our letter notifying of a suspension of CE mark on ARTG product 174123.

Regards [redacted]

[redacted]

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GYTECH PTY LTD
PO BOX 76, ARMADALE NORTH VICTORIA AUSTRALIA 3143
T [redacted] F [redacted] M [redacted]
WWW.GYTECH.COM.AU

GYTECH PTY LTD
SPECIALISED MEDICAL EQUIPMENT & CONSUMABLES

23 July 2014

The Manager
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

**ESSURE System (AUST R 174123) - Class III Medical Device - Contraceptive, tubal occlusion, insert. Suspension of the NSAI Quality Management System and CE Mark certificates for Essure**

It is our objective to ensure you are kept up-to-date about new information concerning our products. As such, we wish to inform you herewith of the temporary suspension of the NSAI Quality Management System and CE Mark certificates for our medical device Essure®.

**Background**
Essure is a permanent birth control method that was approved by the FDA in 2002 and the CE certificate was granted in 2001. Essure has a well-documented benefit-risk profile, with several hundred peer-reviewed publications and abstracts supporting the product's efficacy and safety profile. Approximately 750,000 women worldwide rely on the Essure procedure for permanent birth control.

The first CE Mark certificate was issued by NSAI on February 9, 2001 for the Essure model ESS305, currently placed on the market in the EEA, the CE Mark certificate was issued on June 9, 2006.

The legal manufacturer of Essure is BayerHealthcare LLC (USA) and the Australian sponsor is Gytech Pty Ltd. The product was included in the ARTG in July 2010 and its entry is ARTG No 174123.

**Notification by NSAI**
Bayer was informed by the Notified Body National Standards Authority of Ireland (NSAI) on July 14th about a temporary suspension of the NSAI Quality Management System and CE Mark certificates for Essure as a result of NSAI audit findings at the Essure legal manufacturer Bayer Healthcare LLC, Milpitas, USA. The findings relate to procedural regulatory and contractual requirements. To date, all available data for Essure indicate a positive benefit-risk profile.

Bayer have immediately complied with the NSAI request to temporarily halt the distribution of the product from Bayer controlled warehouses, until this matter is resolved.

A recall of the product from the market is not required by this decision.

Bayer is working closely with the NSAI and is confident that this matter will be resolved soon. Therefore, the suspension is expected to be a temporary matter.

PO Box 76, Armadale North, Victoria 3143
T: [redacted] F: [redacted]
ABN: 12 076 599 570

Bayer has advised that it will inform all contracted external distributors about this matter. It has advised that, we, as a distributor, are not directly affected and can continue delivering products supplied before the effective date.

Gytech will continue to keep you updated on efficacy, safety and quality related matters related to Essure in line with our reporting obligations.

Gytech was advised of the NSAI action on 21 July 2014 and has immediately taken steps to advise the TGA, in accordance with its regulatory obligations. We will keep you informed of any further developments relating to the suspension of the NSAI Quality Management and CE Mark certificates for our medical device Essure, when they are communicated to us by Bayer. Please advise us of what, if any, additional steps you require us to take in relation to this matter.

Please do not hesitate to contact us should you have any further questions regarding these matters.

Sincerely,

Director

PO Box 76, Armadale North, Victoria 3143
T: [redacted] F: [redacted]
ABN: 12 076 599 570