From: [redacted]
To: Devices; [redacted]
Cc: [redacted]
Subject: Essure - ARTG 174123 - Lifting of temporary CE suspension
Date: Friday, 12 September 2014 2:02:18 PM
Attachments: image001.jpg
TGA letter 12 September 2014.pdf

Dear Office of Devices,

Please find attached our letter notifying of the lift of the temporary CE suspension on ARTG 174123.

Regards, [redacted]

[redacted]

GYTECH PTY LTD
PO BOX 76, ARMADALE NORTH VICTORIA AUSTRALIA 3143
T [redacted] F [redacted] M [redacted]
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GYTECH PTY LTD
SPECIALISED MEDICAL EQUIPMENT & CONSUMABLES

12 September 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. Lift of the temporary suspension of the 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, to follow-up on the information previously provided on the temporary suspension of the Quality Management System (QMS) and CE Mark certificates for our medical device ESSURE, we are pleased to inform you that the suspension of the QMS and CE Mark certificates for ESSURE was lifted by the Notified Body National Standards Authority of Ireland (NSAI) on 09 September 2014 with immediate effect.

Background

On 14 July 2014 Bayer was informed by NSAI of the temporary suspension of the QMS and CE Mark certificates for ESSURE as a result of NSAI audit findings at the ESSURE legal manufacturer Bayer Healthcare LLC, Milpitas, USA.

Bayer submitted all requested information to NSAI to satisfy all requirements. A re-certification audit at the legal manufacturer Bayer Healthcare LLC, Milpitas, USA was completed successfully on 27 – 28 August 2014, and the CE Mark and QMS certificates were reinstated by NSAI on 09 September 2014.

Please note that the temporary suspension was at no time a product quality or safety related issue.

Consequences following the lifting of the suspension of the QMS and CE Mark certificates

Bayer has immediately resumed the distribution of the CE marked product. Bayer will inform all contracted external distributors about the lifting of the suspension of the certificates.

Bayer and Gytech will continue to keep you updated on efficacy, safety and quality related matters for ESSURE inline with our reporting obligations in Australia.

Please do not hesitate to contact us should you have any further question on these matters.

Sincerely,

[redacted]
Director

T: [redacted] F: [redacted]
ABN: 12 076 599 570