From: [redacted]
To: Post Market Devices
Cc: [redacted]
Subject: File Reference: 2014/039228 - ARTG 174123
Date: Friday, 8 August 2014 10:02:13 AM
Attachments: image003.jpg
File Reference 2014 039228 8 August 2014.pdf

To the Office of Product Review,

Please find attached our response to your requested for additional information in your letter dated 25th July 2014.

If you require any further information please contact [redacted] at [redacted] or on [redacted]

Regards, [redacted]

[redacted]

_____

Gytech Pty Ltd
PO Box 76, Armadale North Victoria Australia 3143
T [redacted] F [redacted] M [redacted]
www.gytech.com.au

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GYTECH PTY LTD
SPECIALISED MEDICAL EQUIPMENT & CONSUMABLES

8 August 2014

Device Vigilance Monitoring Section
Office of Product Review
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam,

Re: File Reference: 2014/039228 – ARTG Number 174123

As per your letter dated 25th July, please find below the response in relation to the details of the non-conformities identified the NSAI audit.

The observations by the notified body, the National Standards Authority of Ireland (NSAI), relate to procedural regulatory and contractual requirements.

Of particular concern to NSAI leading to the temporary suspension of the CE Mark and NSAI Quality Management System (QMS) Certificates has been a deficiency in effective customer complaint and incident reporting processes to the notified body, and failures to notify NSAI of EU vigilance reports as required by contractual arrangements. However, Bayer has continued to meet its legal obligations to submit vigilance reports to relevant national authorities.

As the safety and performance of Essure is not affected, a safety alert or a recall of Essure has not been required by NSAI. The product on the market was legally manufactured and placed on the market before the suspension date of the CE Mark and the Quality Management System Certificates. Additionally, neither safety nor technical quality concerns were raised by NSAI.

The temporary suspension of the CE Mark and Quality Management System Certificates for Bayer Healthcare LLC, Milpitas CA, USA and the underlying audit findings, do not affect the benefit risk assessment or performance of the Essure product. We confirm that the safety and technical quality of the product is not affected. Bayer has no information that would suggest any deviation from the essential requirements for safety and performance of Essure as defined in Annex I of the Medical Device Directive 93/42/EEC or in GHTF/SG1/N68:2012 - Essential Principles of Safety and Performance of Medical Devices.

A field safety corrective action /field safety notice (FSCA/FSN) of the product Essure from the market has not been required, as there is no evidence that would necessitate any field safety corrective activity according to EU Medical Device Directive Guidance document (MEDDEV 2.12.1.) or Australian regulatory guidelines for medical devices (ARGMD). The products in the market were legally manufactured and placed on the market before the date of the temporary suspension of the CE mark and the Quality Management System Certificates. Additionally, neither safety nor technical quality concerns were raised by NSAI.

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

Bayer HealthCare LLC is in the process of responding to the audit findings to the notified body NSAI. Bayer HealthCare LLC submitted its initial response with a time schedule for further activities to NSAI on July 24, 2014. This response document addressed the root cause of the findings and proposed corrections and corrective actions. Bayer is confident that this matter will be resolved soon. The suspension is expected to be a temporary matter.

Please do not hesitate to contact us should you have any further questions regarding this matter.

Regards,

[redacted]

Director

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