Australian Government

Department of Health
Therapeutic Goods Administration

# [USE THIS TEMPLATE FOR *MEDICAL DEVICES* THAT ARE OFFICIAL SAMPLES I.E. TESTED UNDER PART 5 OF THE TG REGS]

File Reference: 20##/######
Sent by email

The Regulatory Affairs Manager
Sponsor Name
Sponsor Address
Suburb State Postcode
Email: <Enter recipient's email address – this must come from eBS – check with Sponsor to make sure it is accurate>

Dear Title Surname,

**GOODS DO NOT COMPLY WITH APPLICABLE REQUIREMENTS**

**Notice under reg 29 of the *Therapeutic Goods Regulations 1990* to [Sponsor Name] setting out the results of the examination and analysis of 'medical device name'.**

| | |
|---|---|
| **ARTG Number:** | ARTG number / or not applicable if not on the ARTG |
| **Product Name:** | From the ARTG |
| **Intended Purpose:** | From the ARTG |
| **Device Class:** | xxx |
| **Batch Number:** | xxx |
| **Expiry Date:** | xxx |
| **TGA Sample Number:** | xxx |

I refer to the above medical device included in the name of [#insert name of sponsor] OR [#IF NOT ON THE ARTG INSERT: of which you are the sponsor] (**you**).

As set out in this notice, I am writing to inform you of the results of examination and analysis of the above medical device.

**Official and Responsible analysts**

Under reg 25(1) of *Therapeutic Goods Regulations 1990* (**Regulations**), I have been appointed by a delegate of the Secretary as an official analyst.

Under reg 25(3)(c), I have nominated a responsible analyst for examining and testing a sample of the above mentioned medical device.

**Background**

[**#Option A**] On [#insert date], a delegate of the Secretary requested you provide samples of the above mentioned medical device in accordance with the condition imposed on the goods under s 41FN(2) of the *Therapeutic Goods Act 1989* (**Act**). On [#insert date], you delivered to the delegate samples of the goods.

The goods have been received and stored in accordance with reg 26A and 27(1) of the Regulations.

[#delete option A if this is not applicable]

**0R**

[**#Option B**] On [#insert date], an authorised officer (authorised by the Secretary), entered the premises of [#insert manufacturer or wholesaler including address] and in accordance with the Regulations, took samples of the above mentioned goods.

The goods have been taken and stored in accordance with reg 26 and 27(1) of the Regulations.

[#delete option B if this is not applicable]

The sample of the above mentioned medical device was tested by the TGA's Laboratories as part of routine surveillance of products on the Australian market / an incident investigation on (insert date).

**Examination and testing of sample**

Under reg 27 of the Regulations, I am required to arrange for:

- an analysis of the sample by relevant tests set out in reg 28 of the Regulations to the extent I consider necessary to establish:
    - the quantity and quality of goods comprising the sample; and
    - the goods from which the sample was taken comply with the applicable provisions of the essential principles (in schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*)) and any conditions relating to matters mentioned in s 41FO(2)(d) of the Act;
- an examination of the goods, the label (if any) relating to the goods and the packaging of the goods, to determine whether the goods comply with the labelling, packaging and other requirements (including requirements relating to advertising) applicable to the goods.

Under reg 28 of the Regulations, each of the following is a test for determining whether a particular kind of medical device complies with the applicable provisions of the essential principles:

- a test specified in a medical device standard or conformity assessment standard for the kind of device;
- a test accepted for the purpose of issuing a conformity assessment certificate in respect of the kind of device;
- a test required under paragraph 41FO(2)(d) of the Act as a condition of inclusion of the kind of device in the Register;

- any other suitable test that the Secretary requires to be carried out in respect of the kind of device for the purpose of demonstrating compliance with the applicable provisions of the essential principles.

In accordance with reg 28 of the Regulations, the sample was tested for compliance with the requirements of

- insert relevant test;
- [#insert any other relevant tests. Regulation 27 deals with labels and packaging and this is dealt with separately below.]

In accordance with reg 27 of the Regulations, I have also examined the goods, the labelling relating to the goods and the packaging of the goods to determine whether the goods comply with the labelling, packaging and other requirements applicable to the goods, including [# clause 13 in schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*].

**Certificate of official analyst**

As required by reg 29(1) of the Regulations, please find enclosed a Certificate of Official Analyst that sets out the results of my examination and analysis. As you will see, it indicates that the above medical device does not comply with the applicable provisions of the essential principles. DO NOT INCLUDE LABELS/PACKAGING HERE – THEY ARE DEALT WITH BELOW [#delete this note].

In particular:

- Set out the provisions of the essential principles that the goods do not comply with and explain why the goods do not comply with those provisions of the essential principles;

[#If there are any packaging and/or labelling issues insert: Also, the above mentioned product does not comply with labelling, packaging or other requirements applicable to the goods. In particular:

- [#insert details, e.g., how the goods do not comply with clause 13 in schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*]

As the sample was taken under reg 25(3), a copy of the Certificate of Official Analyst has also been sent to [#insert the name of the person from whom the sample was taken if that person is not the sponsor – delete if not applicable].

**Action to be taken by you**

- You are requested to immediately quarantine stock from the affected batch that has not been distributed.
- Your comments on these laboratory test results are invited. Please provide comments on the test results to [name] at [email].

Note: consider whether any action is consistent with the Uniform Recall Procedure for Therapeutic Goods. [#delete this note]

You are requested to provide the following information by close of business [insert letter date + 7 days]: <delete or add as required>

- Confirmation of quarantine of stock from the affected batch that has not been distributed
- The number of units of this batch in stock

- The number of units of this batch distributed to date
- A list of other batches of the same product that are currently held in stock and are within the expiry date
- Confirm if any units have been exported
- Evidence that other batches of the same product on the market are of acceptable quality.

Note: the power to request this information does not arise under the Regulations and you are requesting it voluntarily to manage risk. However, there are statutory powers under the Act to request information, e.g., s 31 [#delete this note]

You are also requested to provide by close of business [insert letter date +21 calendar days]:

- Any information you consider relevant to the TGA's consideration of the enclosed test results.
- The manufacturer's Certificate of Analysis for the batch tested
- The manufacturers methods and specifications for this product
- (INCLUDE THE FOLLOWING FOR STERILITY TEST FAILURES – OTHERWISE DELETE)
- The identity of the site of sterilisation
- The sterilisation process parameters for the affected batch
- Physical and microbiological performance qualification for the sterilisation process
- The sterile barrier integrity reports

**Entitlement to Review**

You may request for the results of the analysis referred to in the certificate to be reviewed in accordance with reg 30 of the Regulations.

Under reg 30 of the Regulations, you must send the Secretary evidence in writing establishing that the goods do conform with the specified standard or comply with an applicable requirement.

A request for review (and supporting evidence) is to be made not later than 21 days after you received the certificate.

If you cannot meet the 21 day time frame, you should write as soon as possible to request an extension of time. Under reg 30(3) of the Regulations, I am required to extend the period of 21 days if it is not reasonable to expect you to provide the evidence within 21 days.

In accordance with reg 30(4) of the Regulations, the written evidence accompanying your request for review must include a certificate from an analyst who has appropriate qualifications and experience setting out:

- a statement that the analyst has analysed a part of the same sample, or a similar sample from the same batch of the goods; and
- the results of that analysis; and
- details of the tests used in the analysis.

**Further Information**

Your early response in writing to this matter, and confirmation of receipt of this letter, is requested. If you have any queries regarding testing of this product, please do not hesitate to contact me directly on (02) 6232 [ext] or via email at name@health.gov.au.

Please note that these results will be published on the TGA website at http://www.tga.gov.au/ws-labs-index once the regulatory outcome of this matter is concluded.

Yours sincerely

Responsible Analyst Note: needs to be signed by the Responsible Analyst [#delete this note]
[name]
[position]
[section]
Laboratories Branch
Email: name@health.gov.au

[date]

Sent by email