From: IRIS

To:

Subject: RE: DEVICE INCIDENT REPORT DIR 65968 [SEC=OFFICIAL]

Date: Thursday, 26 November 2020 1:47:52 PM

Attachments: <u>image006.png</u>

image007.png image008.png

Dear

Thank you for contacting us as soon as you realised the mistake in meeting the due date. I confirm you may have an extension until COB 27 November 2020.

Kin regards,



Devices Post Market Monitoring Section

Medical Devices Surveillance Branch

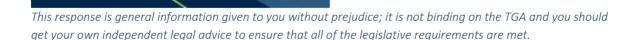
Phone: Email:

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

Please note, the following two **consultations on medical devices** are open until 18 November 2020 and can be accessed through <u>TGA consultation</u>:

- 1. Adverse event reporting of medical devices
- 2. Implementation of an Australian Unique Device Identifier (UDI) system

For ongoing information and updates please subscribe to the TGA's <u>Medical Devices Information</u> and <u>IVDs Information</u> email subscription services.



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From:

Sent: Thursday, 26 November 2020 10:50 AM

To: IRIS <IRIS@health.gov.au>

Subject: DEVICE INCIDENT REPORT DIR 65968

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Attn:

Dear

As per our telephone conversation, I can confirm that we will provide our response to the questions raised by close of business tomorrow 27 November. My apologies for the error on the deadline which I had diarised for tomorrow.

Kind regards



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monashivfgroup.com







