

**From:** IRIS  
**To:** [REDACTED]  
**Subject:** RE: DEVICE INCIDENT REPORT DIR 65968 [SEC=OFFICIAL]  
**Date:** Thursday, 26 November 2020 1:47:52 PM  
**Attachments:** [image006.png](#)  
[image007.png](#)  
[image008.png](#)

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Dear [REDACTED]

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,

[REDACTED]

[REDACTED]

[REDACTED]

Devices Post Market Monitoring Section  
Medical Devices Surveillance Branch

Phone: [REDACTED]

Email: [REDACTED]

Therapeutic Goods Administration  
Department of Health  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)

Please note, the following two **consultations on medical devices** are open until 18 November 2020 and can be accessed through [TGA consultation](#):

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 [Medical Devices Information](#) and [IVDs Information](#) email subscription services.

[REDACTED]

*This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.*

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**From:** [REDACTED]  
**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: [REDACTED]

Dear [REDACTED]

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

[REDACTED]  
[REDACTED]

T. [REDACTED] - M. [REDACTED] - F. [REDACTED]

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