

From: [REDACTED]
To: [REDACTED]
Subject: FYI - Monash IVF Group response received - TGA Request for Information - DIR 65968 - Monash IVF Group [SEC=OFFICIAL]
Date: Friday, 27 November 2020 6:40:04 PM
Attachments: [image002.png](#)
[image003.png](#)
[image004.png](#)
[image005.jpg](#)
[image006.gif](#)
[TGA Response to NI Questions v1.0 27Nov20.pdf](#)
[Group-Adverse-Event-and-Feedback-Policy-v5-0-09Nov20.pdf](#)
[IVD Validation Document - Next Generation Sequencing V1.0.pdf](#)
[Monash IVF Group validation of NGS summary.pdf](#)

Dear all,

Please find attached Monash IVF's response to the requested information in relation to the pre-genetic implantation test (Email also filed in TRIM: [D20-3822434](#)).

I have not forwarded this information to NATA as yet.

Just advising, in case [REDACTED] requires any updates.

Kind regards,

[REDACTED]
From: [REDACTED]

Sent: Friday, 27 November 2020 3:47 PM

To: IRIS

Cc: [REDACTED]

Subject: RE: TGA Request for Information - DIR 65968 - Monash IVF Group

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Please find attached Monash IVF Group's response with the information requested.

Kind regards

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

Monash IVF Group Limited
Pelaco Building 1
Level 1, 21-31 Goodwood Street
Richmond VIC Australia 3121

monashivfgroup.com



From: [REDACTED]

Sent: Friday, 30 October 2020 1:05 PM

To: [REDACTED]

Subject: TGA Request for Information - DIR 65968 - Monash IVF Group - Response due by COB

26 November 2020 [SEC=OFFICIAL]

Dear [REDACTED]

To assist in the evaluation and resolution of the Device Incident Report (DIR 65968) you recently submitted to the TGA, please provide the information requested in the attached letter and return it to this office **within 20 working days of the date of this letter**, and no later than COB 26/11/2020.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on [REDACTED]

[REDACTED] or email IRIS@health.gov.au.

Yours sincerely,

[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

For ongoing information and updates please subscribe to the TGA's [Medical Devices Information](#) and [IVDs Information](#) email subscription services.



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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