

From: [REDACTED]
To: [REDACTED]
Subject: DIR 65968 - Monash IVF Group - Final report to be submitted [SEC=OFFICIAL]
Date: Thursday, 1 July 2021 3:34:30 PM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)
[image006.png](#)
[image007.png](#)
[image008.png](#)

Dear [REDACTED]

Many thanks for your email. Your original report, DIR 65968, has been returned to your portal awaiting submission of your final report. Once you have submitted the final report we will then review all of the information and consider if any follow-up is required.

Many thanks for your assistance.
Kind regards,

[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

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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: Wednesday, 30 June 2021 2:58 PM
To: [REDACTED] <IMCEAEX-
_O=MONASH+20IVF_OU=EXCHANGE+20ADMINISTRATIVE+20GROUP+20+28FYDIBOHF23SPDLT+29_CN=RECIPIENTS_CN-[REDACTED]>
IRIS <IRIS@health.gov.au>
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.

Dear [REDACTED]

I am writing to provide an update to the notification that we made in October 2020, advising that Monash IVF and Repromed had taken the decision to suspend our non-invasive or cell-free PGT-A screening programme. I can now confirm that the organisation has now decided that this test screening programme will not be re-introduced. This test was placed into voluntary suspension and was removed from our scope of practice on the NATA website. However, we have now requested that this test to be formally withdrawn from our NATA accreditation scope.

Following the suspension, we undertook an open disclosure process with all affected patients. We have since worked with those patients to offer remediation options of counselling support as well as ongoing medical care to enable those who wish to continue their treatment to do so. We will continue to provide information and support to our patients who will be informed of the permanent withdrawal of the test today.

You may be aware that a Group Proceeding, or class action, has been commenced against the organisation and as such we hope that you will understand that we are unable to provide further detail or comment.

Kind regards,

[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.au



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From: [REDACTED]
Sent: Friday, 27 November 2020 3:47 PM
To: 'IRIS@health.gov.au' <IRIS@health.gov.au>
Cc: [REDACTED]
Subject: RE: TGA Request for Information - DIR 65968 - Monash IVF Group

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

Kind regards

[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] or email IRIS@health.gov.au

Yours sincerely,

[REDACTED]

[REDACTED]

Devices Post Market Monitoring Section
Medical Devices Surveillance Branch

Phone [REDACTED]
Email [REDACTED]

Therapeutic Goods Administration
Department of Health
PO Box 100
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