



20/05/2021

Client ID:62078

Diverse Devices Pty Ltd
98 Riley Street
Darlinghurst NSW 2010

s22

NOTIFICATION OF THE CANCELLATION OF A KIND OF MEDICAL DEVICE FROM THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

This letter is in response to your request of 19/05/2021 in which you requested the cancellation of a kind of medical device from the Australian Register of Therapeutic Goods (ARTG).

Decision

The Secretary has cancelled the following entry or entries from the ARTG in accordance with section 41GL(d) of the *Therapeutic Goods Act 1989* (the Act):

ARTG Number	ARTG Name
280883	Diverse Devices Pty Ltd - WIRION Embolic Protection System - Emboli capture guidewire

As the recorded sponsor of these kinds of medical devices you should note that the cancellation is effective from 20/05/2021.

You are reminded that under the Act, both criminal and civil penalties may apply to the import, export, or supply of medical devices that are not included in the ARTG and are not the subject of an exemption, approval or authority under the Act.

Financial matters

It is important to note that you may have ongoing financial and related obligations in respect of the cancelled entry or entries:

- You will remain liable for any outstanding annual charges for any entry or entries which were active on the ARTG on or after 1 July of the financial year in which the entry or entries were cancelled.
- If an entry or entries were eligible to be exempt from annual charges under the TGA's annual charge exemption (ACE) scheme in the financial year in which the entry or entries were cancelled, you (the sponsor) must make a final declaration of \$0 turnover for the entry or entries in the declaration period commencing on the next 1 July, but only if the entry or entries were of \$0 turnover.
- Making a final declaration of \$0 turnover will have the effect of confirming the ACE on the entry or entries for the financial year in which the entry or entries were cancelled. Similarly, the entry or entries will not incur any

annual charges, and likewise you will not be required to provide any further declarations in respect of the entry or entries in later financial years after the year the entry or entries were cancelled.

Requesting revocation of this cancellation under section 41GLA

If you wish to have the inclusion of the kind of medical device/s referred to above reinstated in the ARTG you can make a request under section 41GLA of the Act. Any such request must:

- Be made within 90 days of the cancellation, and
- Be accompanied by the prescribed reinstatement fee.

Further information and the reinstatement form are available on the TGA website at <https://www.tga.gov.au/form/request-reinstate-entry-australian-register-therapeutic-goods-artg>. Should you wish to reinstate an entry, please send your request and completed form to accountsrec@health.gov.au.

If the entries are reinstated under section 41GLA, the cancellation is taken never to have occurred.

Review Rights

This decision is an initial decision within the meaning of subsection 60(1) of the Act. You may request the Minister to reconsider the decision within 90 days after the date of receipt of this letter. Attachment A sets out the details of how to apply for a Ministerial review of the decision.

However, as stated above, if you wish to have your entry reinstated, you may prefer to simply make a request under section 41GLA.

Please note that under section 41GP of the Act, the TGA is required to publish in the Commonwealth Gazette or on the TGA website particulars about all cancellations of medical devices, including those initiated by the sponsor.

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Please note that in relation to reinstatement of an entry on the ARTG under section 60, if the delegate agrees to reinstate the entry the reinstatement will become effective from a future prescribed date i.e. the cancellation remains effective until the reinstatement date.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989*" and should include the following:

- A copy of the initial decision notification letter (or other evidence of notification);
- Identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- Any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- An email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and copied to '**decision.review@health.gov.au**'

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.