Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Application ID: DV-2023-CR-00934-1
TGA Reference: E23-503799

Precise Medical Supplies Pty Ltd

Email: bgregory@medicaltechnology.com.au

Attention: Bruce Gregory

**Notice under section 9D of the *Therapeutic Goods Act 1989* of decision to vary ARTG inclusions for medical devices**

| ARTG | GMDN code and term | Class |
|---|---|---|
| 139493 | 45230 Tissue reconstructive material, synthetic, silicone, block | Class IIb |

As a delegate of the Secretary of the Department of Health and Aged Care (the Secretary) for the purposes of section 9D of the *Therapeutic Goods Act 1989* (the Act), I have decided to vary the Australian Register of Therapeutic Goods (ARTG) under subsection 9D(3D) of the Act following your request on the basis that the information provided for this variation does not indicate any reduction in the quality, safety or performance of the kind of medical devices for the purposes for which these devices are intended to be used.

I have amended the abovementioned ARTG entry, as I am satisfied that the sufficient evidence of the application of the appropriate conformity assessment procedures to the kinds of medical devices has been provided to the TGA.

Therefore, I have varied the following information:

**Update manufacturer evidence:**

**To:**
DV-2020-MC-29352-1

**Date of amendment:** 27 March 2023

**Relevant Legislation:**

- *Therapeutic Goods Act 1989*
  https://www.legislation.gov.au/Series/C2004A03952
- *Therapeutic Goods (Medical Device) Regulations 2002*
  https://www.legislation.gov.au/Series/F2002B00237

**Sponsors' ongoing regulatory responsibilities**
Australian sponsors of medical devices have ongoing regulatory responsibilities for the medical devices they supply to the Australian market.

The continued inclusion of the devices of the kind in the ARTG is subject to payment of annual charges.

**Ongoing monitoring of quality, safety and performance**
Therapeutic goods on the ARTG are subject to ongoing monitoring of their quality, safety and performance. At any time, the ARTG entry may be selected for a review to verify compliance of the goods with the regulatory requirements.

**Review of the decision under section 60 of the Act**
Should you wish to seek a review of my decision to vary the ARTG entry, your rights of review are outlined in Attachment A to this letter.

Yours sincerely

Signed and authorised by

Mariam Nasreen
[Signed electronically]
Delegate of the Secretary for the purposes of section 9D of the Act
Medical Devices Authorisation Branch
30 March 2023

**Review Rights**

**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 in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. 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 this function 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 making 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.

**Guidelines for requesting reconsideration of an initial decision**

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website <https://www.tga.gov.au/reconsideration-reviewable-initial-decisions> for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this 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: '**decision.review@health.gov.au**'

Subject: "**<insert name of person/company making request>** - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989*"

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "… - Email 1 of 3", "… - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a request for reconsideration. If the Minister (or

the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

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.

**NOTE:** This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.