Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only

Reference: DB24-1306878

Special Access Scheme – Category B

Patient details

Patient initials	Gender	DOB	MRN
s22	s22	s22	

Diagnosis(es)	Previous SAS No.
prostate cancer	

Indication
Prostate cancer

Clinical justification for use of product
localised intermediate grade prostate cancer in a patient aware of the pros and cons of the gold standard robot prostatectomy and radiotherapy but does not wish to tolerate the side effects

Product details

Medicine or Biological		Medical Device	
Trade Name		**Trade name** Profocal Rx	
Active ingredient(s)		**Product description** ProFocal Rx	
Dosage form	**Strength**	**Model Number / Variant** Focal Laser Delivery System	
Route of administration	**Dose & frequency**	**Sponsor / Supplier** Medilogical PTY LTD	**Manufacturer** Medilogical
Sponsor / Supplier		**No of units to be supplied** 1	**Intended date of use** s22
Expected duration of treatment		**Expected duration of treatment** 3 Hour(s)	

Health Practitioner Details

Prescribing health practitioner details		Submitter details (if different from prescriber)	
First name s22	**Surname** s22	**Business or practice name**	
AHPRA ID s22	**Health practitioner type** Medical Practitioner	**First name**	**Surname**
Email s22		**Health practitioner type**	
Principal practice address s22		**Email**	
Submitter's signature **Electronically signed by** s22		**Date** 02 Oct 2024	

Supporting information

Additional information

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only

Reference: DB24-1306886

Special Access Scheme – Category B

Patient details

Patient initials	Gender	DOB	MRN
s22	s22	s22	

Diagnosis(es)	Previous SAS No.
prostate cancer	

Indication
Prostate cancer

Clinical justification for use of product
localised intermediate grade prostate cancer in a patient aware of the pros and cons of the gold standard robot prostatectomy and radiotherapy but does not wish to tolerate the side effects

Product details

Medicine or Biological		Medical Device	
Trade Name		**Trade name** Profocal Rx	
Active ingredient(s)		**Product description** ProFocal Rx	
Dosage form	**Strength**	**Model Number / Variant** Focal Laser Delivery System	
Route of administration	**Dose & frequency**	**Sponsor / Supplier** Medilogical PTY LTD	**Manufacturer** Medilogical
Sponsor / Supplier		**No of units to be supplied** 1	**Intended date of use** s22
Expected duration of treatment		**Expected duration of treatment** 3 Hour(s)	

Health Practitioner Details

Prescribing health practitioner details		Submitter details (if different from prescriber)	
First name s22	**Surname** s22	**Business or practice name**	
AHPRA ID s22	**Health practitioner type** Medical Practitioner	**First name**	**Surname**
Email s22		**Health practitioner type**	
Principal practice address s22		**Email**	
Submitter's signature **Electronically signed by** s22		**Date** 02 Oct 2024	

Supporting information

Additional information

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only

Reference: DB24-1306889

Special Access Scheme – Category B

Patient details

Patient initials	Gender	DOB	MRN
s22	s22	s22	

Diagnosis(es)	Previous SAS No.
prostate cancer	

Indication
Prostate cancer

Clinical justification for use of product
localised intermediate grade prostate cancer in a patient aware of the pros and cons of the gold standard robot prostatectomy and radiotherapy but does not wish to tolerate the side effects

Product details

Medicine or Biological		Medical Device	
Trade Name		**Trade name** Profocal Rx	
Active ingredient(s)		**Product description** ProFocal Rx	
Dosage form	**Strength**	**Model Number / Variant** Focal Laser Delivery System	
Route of administration	**Dose & frequency**	**Sponsor / Supplier** Medilogical PTY LTD	**Manufacturer** Medilogical
Sponsor / Supplier		**No of units to be supplied** 1	**Intended date of use** 12 Oct 2024
Expected duration of treatment		**Expected duration of treatment** 3 Hour(s)	

Health Practitioner Details

Prescribing health practitioner details		Submitter details (if different from prescriber)	
First name s22	**Surname** s22	**Business or practice name**	
AHPRA ID s22	**Health practitioner type** Medical Practitioner	**First name**	**Surname**
Email s22		**Health practitioner type**	
Principal practice address s22		**Email**	
Submitter's signature **Electronically signed by** s22		**Date** 02 Oct 2024	

Supporting information

Additional information

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

s22 [redacted]

Notice of decision to grant an approval
under paragraph 41HB(1)(d) of the *Therapeutic Goods Act 1989*
(Special Access Scheme – Category B)

I refer to the application made on 02 Oct 2024 seeking approval by the Secretary of the Department of Health and Aged Care to a health practitioner for the importation into, exportation from, or the supply in Australia of a specified medical device or kind of medical device (other than medical devices included in the Australian Register of Therapeutic Goods (**Register**) or exempt devices) for use in the treatment of another person in accordance with paragraph 41HB(1)(d) of the *Therapeutic Goods Act 1989* (**the Act**).

This is a notice of decision given to you in accordance with subsection 41HB(6) of the Act.

Decision

I am a delegate of the Secretary of the Department of Health and Aged Care for the purposes of subsection 41HB(1) of the Act. I have decided to grant approval to s22 [redacted] (the **approval holder**) identified in column 1 of Schedule 1 to this notice to import into, export from, or supply in Australia a specified medical device or kind of medical device identified in column 2 of Schedule 1 for use in the treatment of the patient identified in column 3.

Reasons for decision

I have decided to grant this approval having considered the application made on 02 Oct 2024 and the information provided with that application.

In making this decision, I am satisfied that:

(a) the specified medical device or kind of medical device is not included in the Register or otherwise exempt from the requirement to include the device in the Register;

(b) the importation into, the exportation from, or the supply in Australia of the specified medical device or kind of medical device is for use in the treatment of the patient; and

(c) the approval holder is a health practitioner within the meaning of the Act.

Conditions

This approval is granted subject to the following conditions imposed by me in accordance with subsection 41HB(2) of the Act:

1. the approval holder must only import into, export from, or supply in Australia the specified medical device or kind of medical device for use in the treatment of the patient in the manner described for the Approved medical device or kind of medical device information on this notice (if any);
2. the approval holder, and the patient (or the person with the legal authority to consent to the treatment on behalf of the patient) must accept responsibility for the outcome of the use of the specified medical device or kind of medical device;
3. the approval holder must obtain and record informed consent from each patient (or the person with the legal authority to consent to the treatment on behalf of the patient) in relation to the proposed use of the product, in accordance with professional practice standards and the AHPRA Code of Conduct;
4. the approval holder must report any suspected adverse event associated with the use of the specified medical device or kind of medical device to the TGA within 15 calendar days after the approval holder becomes aware of the adverse event;
5. the approval holder must adhere to all standards of professional practice and conduct, as governed by the relevant professional regulatory authority;
6. the approval holder must not use this approval for the importation into Australia, the exportation from Australia, or the supply in Australia, of the specified medical device or kind of medical device, if it is included in the Register or is exempted from inclusion in the Register during the period of approval.

Please note that it is the responsibility of the approval holder to arrange for the importation into, the exportation from, or the supply in Australia of the specified medical device or kind of medical device and to provide evidence of this approval to the person or persons with whom the importation into, the exportation from or the supply in Australia is arranged.

Period of approval

This approval has effect for a period of 3 Month(s) commencing on the date of this notice, unless the Secretary (or a delegate) decides to revoke the approval.

Dated 02 Oct 2024

s22 [redacted]
Delegate of the Secretary
Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

Schedule 1

Reference: DB24-1306889

Column 1 **Approval holder**	**Column 2** **Specified medical device or kind of medical device**	**Column 3** **Patient**	**Column 4** **Conditions**
s22 [redacted] s22 [redacted]	*Device:* ProFocal Rx *Product description (including variant):* Focal Laser Delivery System *Sponsor/Supplier:* Medlogical Innovations Pty Ltd	*Patient initials:* s22 [redacted] *Patient gender:* s22 [redacted] *Patient DOB:* s22 [redacted]	*Purpose:* Prostate cancer

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

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/resources/resource/guidance/guidance-requesting-reconsideration-initial-decision> 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"

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

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.

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Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22 [redacted]

Notice of decision to grant an approval
under paragraph 41HB(1)(d) of the *Therapeutic Goods Act 1989*
(Special Access Scheme – Category B)

I refer to the application made on 02 Oct 2024 seeking approval by the Secretary of the Department of Health and Aged Care to a health practitioner for the importation into, exportation from, or the supply in Australia of a specified medical device or kind of medical device (other than medical devices included in the Australian Register of Therapeutic Goods (**Register**) or exempt devices) for use in the treatment of another person in accordance with paragraph 41HB(1)(d) of the *Therapeutic Goods Act 1989* (**the Act**).

This is a notice of decision given to you in accordance with subsection 41HB(6) of the Act.

Decision

I am a delegate of the Secretary of the Department of Health and Aged Care for the purposes of subsection 41HB(1) of the Act. I have decided to grant approval to s22 [redacted] (the **approval holder**) identified in column 1 of Schedule 1 to this notice to import into, export from, or supply in Australia a specified medical device or kind of medical device identified in column 2 of Schedule 1 for use in the treatment of the patient identified in column 3.

Reasons for decision

I have decided to grant this approval having considered the application made on 02 Oct 2024 and the information provided with that application.

In making this decision, I am satisfied that:

(a) the specified medical device or kind of medical device is not included in the Register or otherwise exempt from the requirement to include the device in the Register;

(b) the importation into, the exportation from, or the supply in Australia of the specified medical device or kind of medical device is for use in the treatment of the patient; and

(c) the approval holder is a health practitioner within the meaning of the Act.

Conditions

This approval is granted subject to the following conditions imposed by me in accordance with subsection 41HB(2) of the Act:

1. the approval holder must only import into, export from, or supply in Australia the specified medical device or kind of medical device for use in the treatment of the patient in the manner described for the Approved medical device or kind of medical device information on this notice (if any);
2. the approval holder, and the patient (or the person with the legal authority to consent to the treatment on behalf of the patient) must accept responsibility for the outcome of the use of the specified medical device or kind of medical device;
3. the approval holder must obtain and record informed consent from each patient (or the person with the legal authority to consent to the treatment on behalf of the patient) in relation to the proposed use of the product, in accordance with professional practice standards and the AHPRA Code of Conduct;
4. the approval holder must report any suspected adverse event associated with the use of the specified medical device or kind of medical device to the TGA within 15 calendar days after the approval holder becomes aware of the adverse event;
5. the approval holder must adhere to all standards of professional practice and conduct, as governed by the relevant professional regulatory authority;
6. the approval holder must not use this approval for the importation into Australia, the exportation from Australia, or the supply in Australia, of the specified medical device or kind of medical device, if it is included in the Register or is exempted from inclusion in the Register during the period of approval.

Please note that it is the responsibility of the approval holder to arrange for the importation into, the exportation from, or the supply in Australia of the specified medical device or kind of medical device and to provide evidence of this approval to the person or persons with whom the importation into, the exportation from or the supply in Australia is arranged.

Period of approval

This approval has effect for a period of 3 Month(s) commencing on the date of this notice, unless the Secretary (or a delegate) decides to revoke the approval.

Dated 02 Oct 2024

s22 [redacted]
Delegate of the Secretary
Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

Schedule 1

Reference: DB24-1306878

Column 1 Approval holder	Column 2 Specified medical device or kind of medical device	Column 3 Patient	Column 4 Conditions
s22 [redacted] s22 [redacted]	*Device:* ProFocal Rx *Product description (including variant):* Focal Laser Delivery System *Sponsor/Supplier:* Medlogical Innovations Pty Ltd	*Patient initials:* s22 [redacted] *Patient gender:* s22 [redacted] *Patient DOB:* s22 [redacted]	*Purpose:* Prostate cancer

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- 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"

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
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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.

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Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22 [redacted]

Notice of decision to grant an approval
under paragraph 41HB(1)(d) of the *Therapeutic Goods Act 1989*
(Special Access Scheme – Category B)

I refer to the application made on 02 Oct 2024 seeking approval by the Secretary of the Department of Health and Aged Care to a health practitioner for the importation into, exportation from, or the supply in Australia of a specified medical device or kind of medical device (other than medical devices included in the Australian Register of Therapeutic Goods (**Register**) or exempt devices) for use in the treatment of another person in accordance with paragraph 41HB(1)(d) of the *Therapeutic Goods Act 1989* (**the Act**).

This is a notice of decision given to you in accordance with subsection 41HB(6) of the Act.

Decision

I am a delegate of the Secretary of the Department of Health and Aged Care for the purposes of subsection 41HB(1) of the Act. I have decided to grant approval to s22 [redacted] (the **approval holder**) identified in column 1 of Schedule 1 to this notice to import into, export from, or supply in Australia a specified medical device or kind of medical device identified in column 2 of Schedule 1 for use in the treatment of the patient identified in column 3.

Reasons for decision

I have decided to grant this approval having considered the application made on 02 Oct 2024 and the information provided with that application.

In making this decision, I am satisfied that:

(a) the specified medical device or kind of medical device is not included in the Register or otherwise exempt from the requirement to include the device in the Register;

(b) the importation into, the exportation from, or the supply in Australia of the specified medical device or kind of medical device is for use in the treatment of the patient; and

(c) the approval holder is a health practitioner within the meaning of the Act.

Conditions

This approval is granted subject to the following conditions imposed by me in accordance with subsection 41HB(2) of the Act:

1. the approval holder must only import into, export from, or supply in Australia the specified medical device or kind of medical device for use in the treatment of the patient in the manner described for the Approved medical device or kind of medical device information on this notice (if any);
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4. the approval holder must report any suspected adverse event associated with the use of the specified medical device or kind of medical device to the TGA within 15 calendar days after the approval holder becomes aware of the adverse event;
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Please note that it is the responsibility of the approval holder to arrange for the importation into, the exportation from, or the supply in Australia of the specified medical device or kind of medical device and to provide evidence of this approval to the person or persons with whom the importation into, the exportation from or the supply in Australia is arranged.

Period of approval

This approval has effect for a period of 3 Month(s) commencing on the date of this notice, unless the Secretary (or a delegate) decides to revoke the approval.

Dated 02 Oct 2024

s22 [redacted]
Delegate of the Secretary
Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

Schedule 1

Reference: DB24-1306886

Column 1 Approval holder	Column 2 Specified medical device or kind of medical device	Column 3 Patient	Column 4 Conditions
s22 [redacted] s22 [redacted]	*Device:* ProFocal Rx *Product description (including variant):* Focal Laser Delivery System *Sponsor/Supplier:* Medlogical Innovations Pty Ltd	*Patient initials:* s22 [redacted] *Patient gender:* s22 [redacted] *Patient DOB:* s22 [redacted]	*Purpose:* Prostate cancer

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
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- 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"

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
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https://www.tga.gov.au

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Medlogical Innovations

for approval to supply

Medlogical Innovations - Surgical diode laser system

ARTG Identifier	391492
ARTG Start Date	29/06/2022
Export Names	ProFocal RX
Product Category	Medical Device Included (Export Only) Class 1
GMDN	60341
GMDN Term	Surgical diode laser system
Intended Purpose	Targeted ablation of prostate cancer lesions by focal laser thermal therapy.

Manufacturer Details	Address	Certificate number(s)
Medlogical Innovations	27 Mars Road Lane Coast West , NSW , 2066 Australia	

ARTG Standard Conditions

The above Medical Device Included (Export Only) Class 1 has been entered on the Register subject to the following conditions:

· - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Surgical diode laser system

Product Specific Conditions

No specific conditions have been recorded against this entry.

Document 8

Application Number	Application Date	Priority	Product Type	Product Profile	Product Presentation	Prescriber	Previous SAS Number	Status Reason	Decision Date	Modified On
DA23-0929803	17/05/2023	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System	s22		Completed		17/05/2023 16:40
DA23-0987493	15/08/2023	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		15/08/2023 18:02
DA23-1057450	29/11/2023	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		29/11/2023 21:24
DA23-1068926	14/12/2023	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		14/12/2023 17:45
DA24-1089630	25/01/2024	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		25/01/2024 12:43
DA24-1109002	22/02/2024	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		22/02/2024 17:34
DA24-1116082	4/03/2024	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		4/03/2024 22:29
DA24-1129111	20/03/2024	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		20/03/2024 23:03
DA24-1254582	7/08/2024	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		7/08/2024 21:26
DA24-1254593	7/08/2024	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		7/08/2024 21:32
DA24-1279337	3/09/2024	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		3/09/2024 11:02
DA24-1332328	31/10/2024	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		31/10/2024 8:56
DA25-1449258	27/02/2025	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		27/02/2025 0:03
DA25-1449259	27/02/2025	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		27/02/2025 0:08
DA25-1481712	26/03/2025	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		26/03/2025 23:26
DA25-1481713	26/03/2025	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		26/03/2025 23:29
DA25-1481715	26/03/2025	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		26/03/2025 23:32
DA25-1585514	18/06/2025	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		18/06/2025 21:42
DA25-1585516	18/06/2025	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		18/06/2025 21:46
DA25-1648378	14/08/2025	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		14/08/2025 9:21
DA25-1648386	14/08/2025	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Completed		14/08/2025 9:25
DB24-1306878	2/10/2024	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Approved	2/10/2024	2/10/2024 16:10
DB24-1306886	2/10/2024	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Approved	2/10/2024	2/10/2024 16:10
DB24-1306889	2/10/2024	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Approved	2/10/2024	2/10/2024 16:10
DB25-1620639	21/07/2025	Normal	Medical Device	ProFocal Rx	Focal Laser Delivery System			Cancelled		21/07/2025 13:34

Document 9

Authorised Prescriber Number	Prescriber	Product Type	Product Profile	Product Presentation	Indication	Status Reason	Created On	Modified On
s22	s22	Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Expired	16/09/2022 15:38	15/12/2024 2:00
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Expired	30/09/2022 14:18	20/10/2024 2:00
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Expired	11/10/2022 20:37	11/10/2024 2:00
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Expired	20/10/2022 19:29	20/10/2024 2:00
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Expired	10/03/2023 9:20	7/03/2025 2:00
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Expired	19/05/2023 10:47	30/03/2025 2:00
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Expired	26/06/2023 22:29	20/06/2025 2:00
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Expired	23/07/2023 22:47	20/06/2025 2:00
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Cancelled	15/12/2023 9:41	19/12/2023 9:44
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	5/05/2024 21:11	7/05/2024 10:45
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	25/09/2024 14:50	14/02/2025 14:13
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	2/10/2024 10:30	2/10/2024 15:52
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	5/10/2024 16:08	8/10/2024 13:34
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	11/10/2024 19:03	22/10/2024 21:30
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	27/10/2024 12:18	31/10/2024 12:50
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	31/10/2024 13:26	8/11/2024 14:33
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	21/01/2025 13:17	22/01/2025 15:36
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	20/02/2025 18:37	21/02/2025 14:27
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	21/02/2025 10:48	21/02/2025 14:40
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	3/03/2025 18:32	3/04/2025 17:04
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	8/04/2025 11:51	8/04/2025 13:45
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	23/04/2025 11:52	23/04/2025 15:20
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	19/05/2025 10:33	19/05/2025 20:12
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	20/05/2025 18:00	21/05/2025 9:35
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	20/05/2025 23:51	21/05/2025 9:41
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	19/06/2025 23:58	23/06/2025 16:05
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	20/06/2025 10:15	23/06/2025 16:08
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	21/07/2025 12:16	21/07/2025 18:30
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	13/08/2025 16:56	14/08/2025 10:53
		Medical Device	ProFocal Rx	Focal Laser Delivery System	Prostate cancer	Approved	15/08/2025 11:36	15/08/2025 15:52

Australian Government
Department of Health
Therapeutic Goods Administration

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Add or remove an Agent from your organisation

Complete this form if you wish to authorise or remove an Agent (e.g. a regulatory affairs consultant) or people external to your company to undertake regulatory correspondence with us.

Please note: Agents will have full access to all of your approved records.

TGA Business Services (TBS) Terms and Conditions

Organisation for which the Agent relationship is being amended

Organisation business name:	Medlogical Innovations Pty Ltd
Organisation ID:	TGA 70006
I want to:	☒ Add an Agent ☐ Remove an Agent

Details of Agent

Agency name:	KD&A Pty Ltd		
Agency organisation ID:	42796		
Telephone:	s22 [redacted]	Fax:	N/A

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 8581 Email: ebs@tga.gov.au http://www.tga.gov.au

TGA Health Safety Regulation

Declaration

Printed name:	s22 [redacted]		
Position in organisation:			
Signature:		Date:	s22 [redacted] 1st August 2023

From: s22 [redacted]
To: SAS
Subject: Authorise Prescriber Scheme – Six Monthly Reporting
Date: Thursday, 21 March 2024 1:05:50 PM
Attachments: image013.png
image014.png
six-monthly-report-supply-of-unapproved-therapeutic-goods-by-a-sponsor Jan-Jun2023.pdf
six-monthly-report-supply-of-unapproved-therapeutic-goods-by-a-sponsor Jul-Dec2023.pdf
six-monthly-report-supply-of-unapproved-therapeutic-goods-by-a-sponsor Jul-Dec2022.pdf

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Hello,
Medlogical Innovations, ID 70006.
The ProFocal Console and the associated consumable set, the ProFocal Ablation Set, have been supplied to medical practitioners under the Authorised Prescriber Scheme. Medlogical Innovations has been supplying doctors with the ProFocal Console and ProFocal Ablation Sets since December of 2022. Please find attached the reports covering these reporting periods which detail the quantities of the units supplied.
My hope is that these reports will satisfy our obligations under the Authorised Prescriber Scheme. Please confirm receipt of these reports, and advise if there is any additional information required.
Many thanks,

s22 [redacted]
[redacted]
[redacted]
Unit G01
3 Apollo Place
Lane Cove West, NSW 2066
M: s22 [redacted]
Ph: s22 [redacted]
www.medlogicalinnovations.com

From: Authorised Prescribers <Authorised.Prescribers@health.gov.au>
Sent: Thursday, March 21, 2024 9:29 AM
To: s22 [redacted]@medlogicalinnovations.com>
Subject: AP – Enquiry – Six Monthly Reporting – s22 [redacted] [SEC=OFFICIAL]
Dear s22 [redacted]
Thank you for your email.
Sponsor responsibilities in relation to supplying therapeutic goods under the Authorised Prescriber (AP) scheme can be found in page 22 of the Authorised Prescriber Scheme: Guidance for medical practitioners, Human Research Ethics Committees, specialist colleges and sponsors.
Sponsor responsibilities include ensuring legal supply of products, submitting six-monthly supply reports, ensuring compliance with all applicable standards, and reporting adverse events and defects.
Regulation 47B of the Therapeutic Goods Regulations 1990 outlines the requirement for the sponsor (importer) to submit six-monthly supply reports to the TGA.

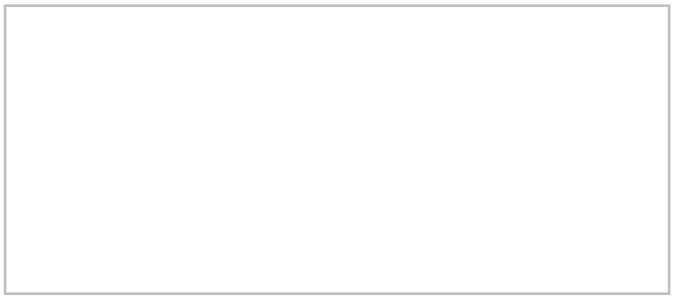
The reports should list each kind of therapeutic good supplied, the number of times supplied to health practitioners and the quantity supplied by the sponsor during the six-month period (as outlined in sub-regulation 47B (5)).
Please complete the TGA's six monthly report template and email the attachment to sas@health.gov.au.
I hope this information is of assistance. If you have any further questions, please do not hesitate to contact us by email to sas@health.gov.au
Kind Regards,
Administrative Support Team

Special Access Section | International Regulatory Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

PO Box 100, Canberra ACT 2606
www.tga.gov.au

From: s22 [redacted]@medlogicalinnovations.com>
Sent: Wednesday, March 20, 2024 12:18 PM
To: TBS Helpdesk <eBS@health.gov.au>
Subject: Query - Authorised Prescriber Reporting

Hello,
Medlogical Innovations, ID 70006.
I would like to discuss some overdue reporting for a sponsor supplying devices to medical practitioners under the authorised prescriber scheme, to determine the best way to close the gap and document the required information to fulfil the obligations. Would it be possible to be put in touch with someone that could direct me as to the best way to report on periods prior to the last 6 months?
Many thanks,
s22 [redacted]
[redacted]
[redacted]
Unit G01
3 Apollo Place
Lane Cove West, NSW 2066
M: s22 [redacted]
Ph: s22 [redacted]
www.medlogicalinnovations.com



Australian Government
Department of Health
Therapeutic Goods Administration

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Six monthly report – supply of unapproved therapeutic goods by a sponsor

Six monthly report required under regulation 47B(1)(c) of the *Therapeutic Goods Regulations 1990*

Please complete one form per sponsor, per reporting period

Details of Sponsor

Name of Sponsor	Medlogical Innovations Pty. Ltd.
Address	G01 3 Apollo Place, Lane Cove West, NSW, 2066
Email address	s22 [redacted] @medlogicalinnovations.com
Phone number	s22 [redacted]
Name and position of authorised person	s22 [redacted]

Reporting period for the six months

(Select the period for which this report applies and complete the year)

☒ 1 January – 30 June 2023

OR

☐ 1 July – 31 December 20

Signature s22 [redacted] Date 21 MAR 2024

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au https://www.tga.gov.au
Reference/Publication (March 2022)

Therapeutic goods supplied to health practitioners

Active ingredient/s* (name and strength) or device name	Trade name	Category of cannabinoid content (medicinal cannabis products only)**	Dosage form* (where applicable)	Quantity per dosage unit (where applicable)	Quantity of units supplied by pathway (Not applicable to nicotine vaping products)		
					Special Access Scheme	Authorised Prescriber Scheme	Total
ProFocal Ablation Set	ProFocal Ablation Set	N/A	N/A	1	N/A	s47	
ProFocal Console	ProFocal Console	N/A	N/A	1	N/A	1	1

Please attach additional pages as required

* Refer to TGA approved terminology where available

** Categories of medicinal cannabis products are available at Medicinal cannabis: Information for health professionals | Therapeutic Goods Administration (TGA):

- Category 1: CBD medicinal cannabis product (CBD ≥98%)
- Category 2: CBD dominant medicinal cannabis product (CBD ≥60% and <98%)
- Category 3: Balanced medicinal cannabis product (CBD <60% and ≥40%)
- Category 4: THC dominant medicinal cannabis product (THC 60-98%)
- Category 5: THC medicinal cannabis product (THC≥98%)

Australian Government
Department of Health
Therapeutic Goods Administration

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Six monthly report – supply of unapproved therapeutic goods by a sponsor

Six monthly report required under regulation 47B(1)(c) of the *Therapeutic Goods Regulations 1990*

Please complete one form per sponsor, per reporting period

Details of Sponsor

Name of Sponsor	Medlogical Innovations Pty. Ltd.
Address	G01 3 Apollo Place, Lane Cove West, NSW, 2066
Email address	s22 [redacted] @medlogicalinnovations.com
Phone number	s22 [redacted]
Name and position of authorised person	s22 [redacted]

Reporting period for the six months

(Select the period for which this report applies and complete the year)

☐ 1 January – 30 June 20__

OR

☒ 1 July – 31 December 2023

Signature s22 [redacted] Date 21 MAR 2024

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au https://www.tga.gov.au
Reference/Publication (March 2022)

Therapeutic goods supplied to health practitioners

Active ingredient/s* (name and strength) or device name	Trade name	Category of cannabinoid content (medicinal cannabis products only)**	Dosage form* (where applicable)	Quantity per dosage unit (where applicable)	Quantity of units supplied by pathway (Not applicable to nicotine vaping products)		
					Special Access Scheme	Authorised Prescriber Scheme	Total
ProFocal Ablation Set	ProFocal Ablation Set	N/A	N/A	1	N/A	s47	
ProFocal Console	ProFocal Console	N/A	N/A	1	N/A	1	1

Please attach additional pages as required

* Refer to TGA approved terminology where available

** Categories of medicinal cannabis products are available at Medicinal cannabis: Information for health professionals | Therapeutic Goods Administration (TGA):

- Category 1: CBD medicinal cannabis product (CBD ≥98%)
- Category 2: CBD dominant medicinal cannabis product (CBD ≥60% and <98%)
- Category 3: Balanced medicinal cannabis product (CBD <60% and ≥40%)
- Category 4: THC dominant medicinal cannabis product (THC 60-98%)
- Category 5: THC medicinal cannabis product (THC≥98%)

Australian Government
Department of Health
Therapeutic Goods Administration

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Six monthly report – supply of unapproved therapeutic goods by a sponsor

Six monthly report required under regulation 47B(1)(c) of the *Therapeutic Goods Regulations 1990*

Please complete one form per sponsor, per reporting period

Details of Sponsor

Name of Sponsor	Medlogical Innovations Pty. Ltd.
Address	G01 3 Apollo Place, Lane Cove West, NSW, 2066
Email address	s22 [redacted]@medlogicalinnovations.com
Phone number	s22 [redacted]
Name and position of authorised person	s22 [redacted]

Reporting period for the six months

(Select the period for which this report applies and complete the year)

☐ 1 January – 30 June 20

OR

☒ 1 July – 31 December 2022

Signature s22 [redacted] Date 21 MAR 2024

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au https://www.tga.gov.au
Reference/Publication (March 2022)

Therapeutic goods supplied to health practitioners

Active ingredient/s* (name and strength) or device name	Trade name	Category of cannabinoid content (medicinal cannabis products only)**	Dosage form* (where applicable)	Quantity per dosage unit (where applicable)	Quantity of units supplied by pathway (Not applicable to nicotine vaping products)		
					Special Access Scheme	Authorised Prescriber Scheme	Total
ProFocal Ablation Set	ProFocal Ablation Set	N/A	N/A	1	N/A	s47	
ProFocal Console	ProFocal Console	N/A	N/A	1	N/A	1	1

Please attach additional pages as required

* Refer to TGA approved terminology where available

** Categories of medicinal cannabis products are available at Medicinal cannabis: Information for health professionals | Therapeutic Goods Administration (TGA):

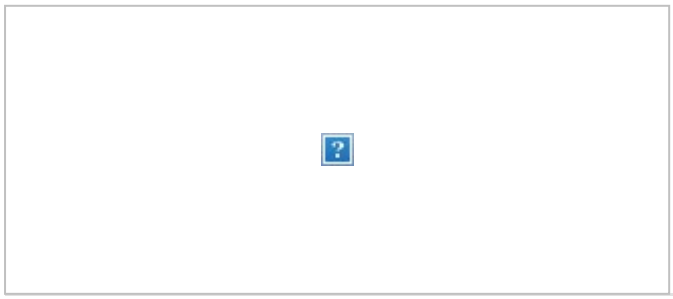
- Category 1: CBD medicinal cannabis product (CBD ≥98%)
- Category 2: CBD dominant medicinal cannabis product (CBD ≥60% and <98%)
- Category 3: Balanced medicinal cannabis product (CBD <60% and ≥40%)
- Category 4: THC dominant medicinal cannabis product (THC 60-98%)
- Category 5: THC medicinal cannabis product (THC≥98%)

From: s22 [redacted]
To: SAS.Support
Subject: RE: Reporting Period Jul-Dec 2024 - Medlogical Innovations
Date: Tuesday, 14 January 2025 9:26:33 AM
Attachments: image001.png
six-monthly-report-supply-unapproved-therapeutic-goods-sponsor Jul-Dec2024.xlsx

---

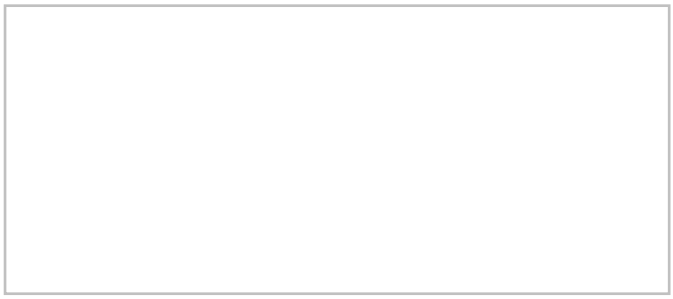
Hello SAS Support Team,
I have noticed that I used the previous (old) form to complete this report which was submitted yesterday, please find the report completed using the new form format attached.
Many thanks,

s22 [redacted]
[redacted]
[redacted]
Unit G01
3 Apollo Place
Lane Cove West, NSW 2066
M: s22 [redacted]
Ph: s22 [redacted]
www.medlogicalinnovations.com



From: s22 [redacted]
Sent: Monday, January 13, 2025 2:37 PM
To: SAS.Support
Subject: Reporting Period Jul-Dec 2024 - Medlogical Innovations
Hello SAS Support Team,
Please find the Medlogical Innovations' six-monthly report for the period of Jul-Dec 2024 attached.
Many thanks,

s22 [redacted]
[redacted]
[redacted]
Unit G01
3 Apollo Place
Lane Cove West, NSW 2066
M: s22 [redacted]
Ph: s22 [redacted]
www.medlogicalinnovations.com



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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Six monthly report - supply of unapproved therapeutic goods by a sponsor

Six monthly report required under regulation 47B(1)(c) of the Therapeutic Goods Regulations 1990

Please complete one form per sponsor, per reporting period

Details of Sponsor

Name of Sponsor	Medlogical Innovations Pty. Ltd.
Address	3 Apollo Place, Lane Cove West, 2066, NSW, Austr
Email Address	s22 [redacted] @medlogicalinnovations.com
Phone Number	s22 [redacted]
Name of authorised person	s22 [redacted]
Position of authorised person	s22 [redacted]

Reporting period for the six months

Please select the relevant reporting period and year for which this report applies.

Available reporting periods are 1 January - 30 June or 1 July - 31 December

Reporting Period: 1 July - 31 December Year: 2024

Declaration

By selecting the box next to the declaration, and typing your name underneath, you are taken to have made the declaration

Reporting requirements

You must report the quantity of each unapproved product you have supplied under the SAS and AP schemes in the relevant tab(s) below

Reporting Periods

1 January to 30 June
1 July to 31 December
You must do this within one month of the reporting period ending

How to report

Fill in this page and any relevant product tabs below
To find out more read the step-by-step guide to completing the form

Therapeutic product type

Medicinal Cannabis Products
Medicine (Non-Medicinal Cannabis) Products
Therapeutic Vapes
Biological Products
Device Products

Completed form to be returned to SAS.Support@health.gov.au

☑ I declare that the information provided in this form is, to the best of my knowledge, complete and correct. I understand giving false or misleading information is a serious offence.

Name s22

V1.0 June 2024

Active ingredient/s (name and strength)	Full cannabinoid profile (Click here for further information on category determination)	Trade name	Category of cannabinoid content	Dosage form (where applicable)	Pack size / total volume (where applicable)	Quantity of packs supplied by Special Access Scheme (SAS) pathway	Quantity of packs supplied by Authorised Prescriber (AP) pathway	Total quantity of packs supplied by pathways
CBD 100mg/mL	*CBD >98%, THC<1%, CBG<1% + other cannabinoids*	*TGA Example*	*Category 1: CBD medicinal cannabis product (CBD =98%)*	*Oral Liquid*	*30mL*	*100*	*0*	*100*

Active ingredient/s (name and strength)	Trade name	Dosage form (where applicable)	Pack size / total volume (where applicable)	Quantity of packs supplied by Special Access Scheme (SAS) pathway	Quantity of packs supplied by Authorised Prescriber (AP) pathway	Total quantity of packs supplied by pathways
Example Ingredient 20mg	*TGA Example*	*Tablet*	*12*	*50*	*50*	*100*

Active ingredient/s (name and strength)	Trade name	Dosage form (where applicable)	Pack size / total volume (where applicable)	Total quantity of packs supplied
Example Ingredient 20mg/mL	*TGA Example*	*Liquid*	*10mL*	*20*

Active ingredient/s (name and strength)	Trade name	Pack size / total volume (where applicable)	Quantity of packs supplied by Special Access Scheme (SAS) pathway	Quantity of packs supplied by Authorised Prescriber (AP) pathway	Total quantity of packs supplied by pathways
Example Ingredient	*TGA Example*	*Optional*	*50*	*0*	*50*

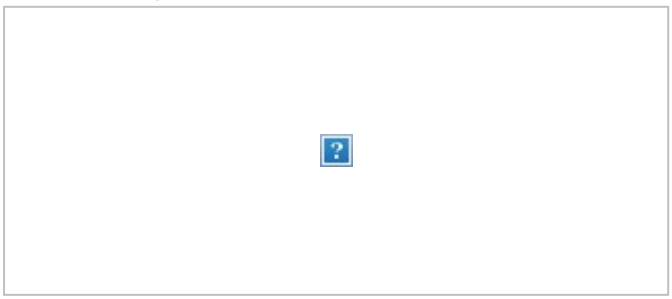
Active ingredient/s (name and strength)	Trade name	Pack size / total volume (where applicable)	Quantity of packs supplied by Special Access Scheme (SAS) pathway	Quantity of packs supplied by Authorised Prescriber (AP) pathway	Total quantity of packs supplied by pathways
Example Device Name	*TGA Example*	*Optional*	*20*	*0*	*20*
ProFocal Ablation Set	ProFocal Ablation Set	1	0	s47	s47
ProFocal Console	ProFocal Console	1	0		

From: s22 [redacted]
To: SAS.Support
Subject: Medlogical Innovations Six Monthly Report - Jan - July 2024
Date: Friday, 28 June 2024 11:20:47 AM
Attachments: image001.png
six-monthly-report-supply-unapproved-therapeutic-goods-sponsor.xlsx

---

Hello,
Please find the Medlogical Innovations' six-monthly report for the Jan-July 2024 period attached.
Best regards,

s22 [redacted]
[redacted]
[redacted]
Unit G01
3 Apollo Place
Lane Cove West, NSW 2066
M: s22 [redacted]
Ph: s22 [redacted]
www.medlogicalinnovations.com



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only

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Six monthly report - supply of unapproved therapeutic goods by a sponsor

Six monthly report required under regulation 47B(1)(c) of the Therapeutic Goods Regulations 1990

Please complete one form per sponsor, per reporting period

Details of Sponsor

Name of Sponsor	Medlogical Innovations Pty. Ltd.
Address	3 Apollo Place, Lane Cove West, 2066, NSW, Austr
Email Address	s22 [redacted] @medlogicalinnovations.com
Phone Number	s22 [redacted]
Name of authorised person	s22 [redacted]
Position of authorised person	s22 [redacted]

Reporting period for the six months

Please select the relevant reporting period and year for which this report applies.

Available reporting periods are 1 January - 30 June or 1 July - 31 December

Reporting Period: 1 January - 30 June Year: 2024

Declaration

By selecting the box next to the declaration, and typing your name underneath, you are taken to have made the declaration

Reporting requirements

You must report the quantity of each unapproved product you have supplied under the SAS and AP schemes in the relevant tab(s) below

Reporting Periods

1 January to 30 June
1 July to 31 December
You must do this within one month of the reporting period ending

How to report

Fill in this page and any relevant product tabs below
To find out more read the step-by-step guide to completing the form

Therapeutic product type

Medicinal Cannabis Products
Medicine (Non-Medicinal Cannabis) Products
Therapeutic Vapes
Biological Products
Device Products

Completed form to be returned to SAS.Support@health.gov.au

☑ I declare that the information provided in this form is, to the best of my knowledge, complete and correct. I understand giving false or misleading information is a serious offence.

Name s22

V1.0 June 2024

Active ingredient/s (name and strength)	Full cannabinoid profile (Click here for further information on category determination)	Trade name	Category of cannabinoid content	Dosage form (where applicable)	Pack size / total volume (where applicable)	Quantity of packs supplied by Special Access Scheme (SAS) pathway	Quantity of packs supplied by Authorised Prescriber (AP) pathway	Total quantity of packs supplied by pathways
CBD 100mg/mL	*CBD >98%, THC<1%, CBG<1% + other cannabinoids*	*TGA Example*	*Category 1: CBD medicinal cannabis product (CBD =98%)*	*Oral Liquid*	*30mL*	*100*	*0*	*100*

Active ingredient/s (name and strength)	Trade name	Dosage form (where applicable)	Pack size / total volume (where applicable)	Quantity of packs supplied by Special Access Scheme (SAS) pathway	Quantity of packs supplied by Authorised Prescriber (AP) pathway	Total quantity of packs supplied by pathways
Example Ingredient 20mg	*TGA Example*	*Tablet*	*12*	*50*	*50*	*100*

Active ingredient/s (name and strength)	Trade name	Dosage form (where applicable)	Pack size / total volume (where applicable)	Total quantity of packs supplied
Example Ingredient 20mg/mL	*TGA Example*	*Liquid*	*10mL*	*20*

Active ingredient/s (name and strength)	Trade name	Pack size / total volume (where applicable)	Quantity of packs supplied by Special Access Scheme (SAS) pathway	Quantity of packs supplied by Authorised Prescriber (AP) pathway	Total quantity of packs supplied by pathways
Example Ingredient	*TGA Example*	*Optional*	*50*	*0*	*50*

Active ingredient/s (name and strength)	Trade name	Pack size / total volume (where applicable)	Quantity of packs supplied by Special Access Scheme (SAS) pathway	Quantity of packs supplied by Authorised Prescriber (AP) pathway	Total quantity of packs supplied by pathways
Example Device Name	*TGA Example*	*Optional*	*20*	*0*	*20*
ProFocal Ablation Set	ProFocal Ablation Set	1	0	s47 [redacted]	s47 [redacted]

From: s22 [redacted]
To: SAS.Support
Cc: s22 [redacted]
Subject: Medlogical Innovations reporting JAN-JUN 2025
Date: Monday, 7 July 2025 12:56:39 PM
Attachments: image001.png
image002.png
six-monthly-report-supply-unapproved-therapeutic-goods-sponsor Medloogical Innovations JAN-JUN 2025.pdf
six-monthly-report-supply-unapproved-therapeutic-goods-sponsor Medloogical Innovations JAN-JUN 2025.xlsx

---

Hello SAS Support Team,
Please find the Medlogical Innovations' six-monthly report for the period of JAN-JUN 2025 attached.
Many thanks,

s22 [redacted]
[redacted]
[redacted]
Medlogical Innovations Pty Ltd
Unit G01, 3 Apollo Place
Lane Cove West, NSW 2066
Mobile: s22 [redacted]
Web: www.medlogicalinnovations.com

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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Please complete one form per sponsor, per reporting period

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Address	3 Apollo Place, Lane Cove West, 2066, NSW, Austr
Email Address	s22 @medlogicalinnovations.com
Phone Number	s22
Name of authorised person	s22
Position of authorised person	s22

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Reporting Period: 1 January - 30 June Year: 2025

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Name: s22

V1.0 June 2024

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Example Device Name	*TGA Example*	*Optional*	*20*	*0*	*20*
ProFocal Ablation Set	ProFocal Ablation Set		1	0	s47
ProFocal Console	ProFocal Console		1	0	s47

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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Phone Number	s22 [redacted]
Name of authorised person	s22 [redacted]
Position of authorised person	s22 [redacted]

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Name: s22 [redacted]

V1.0 June 2024

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Example Ingredient 20mg/mL	*TGA Example*	*Liquid*	*10mL*	*20*

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ProFocal Ablation Set	ProFocal Ablation Set	1	0	s47 [redacted]	s47 [redacted]
ProFocal Console	ProFocal Console	1	0		

From: SAS
To: Devices Clinical Delegate
Cc: s22 [redacted]
Subject: SAS - Devices Enquiry - Adverse Event - s22 [redacted] - Medlogical Innovations [SEC=OFFICIAL]
Date: Friday, 25 October 2024 3:45:59 PM
Attachments: image001.png
image003.png

Dear Devices Delegates,

We have received a devices enquiry which we are unable to provide advice regarding.

We have forwarded the email and request that you review the enquiry and provide a response directly as any further device related enquiries they may have, will likely require a delegate to provide assistance.

If the enquirer requires any assistance with portal or administrative enquiries/concerns, please forward these enquiries to our team so we may investigate further where needed.

If you have any questions, please do not hesitate to contact us by email to sas@health.gov.au

Kind regards,

From 1 July 2024, we will ONLY accept online submissions; hard copy or emailed submissions will not be processed.
Register at https://compliance.health.gov.au/sas/. To troubleshoot, email SAS.Support@health.gov.au.

Administrative Support Team

Special Access Section | International Regulatory Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

PO Box 100, Canberra ACT 2606
www.tga.gov.au

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From: s22 [redacted]@medlogicalinnovations.com>
Sent: Friday, October 25, 2024 3:18 PM
To: Authorised Prescribers <Authorised.Prescribers@health.gov.au>
Cc: s22 [redacted]@medlogicalinnovations.com>

Subject: Request for Information Regarding Potential Adverse Event

Hello,

Medlogical Innovations is providing the ProFocal Ablation Set and ProFocal Console (together referred to as the ProFocal System) to approved clinicians under the Authorised Prescriber Scheme.

During a communication with one of the clinicians, we have been advised that a patient following surgery using our device has suffered a cardiac event while in recovery. Our device, a minimally invasive therapy used to treat prostate tissue is not believed by the clinician to be linked to the event, however it has occurred within the recovery period after the surgery and so we are unsure here if this may impact our obligations.

It is our understanding that under the AP scheme, that the reporting of AEs is the responsibility of the clinician, and as the issue doesn't appear to be related to the use of the device we do not believe that we are required to report this event. Though to be certain I would like to bring this to your attention and confirm what our obligations may be, if any.

Many thanks for your time,

s22 [redacted]

s22 [redacted]

Unit G01
3 Apollo Place
Lane Cove West, NSW 2066
M: s22 [redacted]
Ph: s22 [redacted]
www.medlogicalinnovations.com

MEDLOGICAL INNOVATIONS

From: Devices Clinical Delegate
To: s22 @medlogicalinnovations.com
Cc: Devices Clinical Delegate
Subject: RE: SAS – Devices Enquiry – Adverse Event – s22 – Medlogical Innovations [SEC=OFFICIAL]
Date: Monday, 28 October 2024 10:02:01 AM
Attachments: image004.png
image005.png

Dear s22

Thank you for your email.

As per the TGA guidance on *"Becoming an authorised prescriber for unapproved therapeutic goods in Australia"*, reporting adverse events associated with the use of 'unapproved' goods is a responsibility of both medical practitioners who become Authorised Prescribers and of sponsors. Further information on the roles and responsibilities of medical practitioners who become Authorised Prescribers and of sponsors can be found at: https://www.tga.gov.au/resources/guidance/becoming-authorised-prescriber-unapproved-therapeutic-goods-australia#roles-and-responsibilities

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I hope this information is of assistance.

Kind regards,

Devices Clinical Delegates

Devices Clinical Evaluation Section | Medical Devices Authorisations Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

PO Box 100, Woden ACT 2606

www.tga.gov.au

From: s22 @medlogicalinnovations.com>

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Many thanks for your time,
s22 [redacted]

s22 [redacted]
[redacted]

Unit G01
3 Apollo Place
Lane Cove West, NSW 2066
M: s22 [redacted]
Ph: s22 [redacted]
www.medlogicalinnovations.com

MEDLOGICAL INNOVATIONS

From: SAS
To: Devices Clinical Delegate
Subject: RE: SAS - Devices Enquiry - Adverse Event - s22 [redacted] - Medlogical Innovations [SEC=OFFICIAL]
Date: Monday, 28 October 2024 10:52:33 AM
Attachments: image002.png
image003.png
image004.png

Dear s22 [redacted]

Thank you for taking carriage of this enquiry and keeping us informed.

Kind regards,

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Administrative Support Team

Special Access Section | International Regulatory Branch
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From: Devices Clinical Delegate <DevicesClinicalDelegate@health.gov.au>
Sent: Monday, October 28, 2024 10:05 AM
To: SAS <sas@health.gov.au>
Cc: s22 [redacted] @Health.gov.au>; s22 [redacted] @Health.gov.au>; Devices Clinical Delegate <DevicesClinicalDelegate@health.gov.au>
Subject: RE: SAS – Devices Enquiry – Adverse Event – s22 [redacted] Medlogical Innovations [SEC=OFFICIAL]

Dear SAS team,

Thank you for your email.

This is just to confirm that I have responded to the enquirer directly.

Kind regards,
s22

s22
Medical Officer
Devices Clinical Evaluation Section

Medical Devices Authorisation Branch
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
PO Box 100, WODEN ACT 2606, Australia
The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: SAS <sas@health.gov.au>
Sent: Friday, 25 October 2024 3:46 PM
To: Devices Clinical Delegate <DevicesClinicalDelegate@health.gov.au>
Cc: s22 @Health.gov.au>; s22
s22 @Health.gov.au>
Subject: SAS – Devices Enquiry – Adverse Event – s22 – Medlogical Innovations [SEC=OFFICIAL]

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s22 [redacted]
[redacted]

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www.medlogicalinnovations.com

MEDLOGICAL
INNOVATIONS

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To: s22 @medlogicalinnovations.com
Cc: Devices Clinical Delegate
Bcc: s22
Subject: RE: SAS – Devices Enquiry – Adverse Event – s22 – Medlogical Innovations [SEC=OFFICIAL]
Date: Monday, 28 October 2024 10:02:01 AM
Attachments: image004.png
image005.png

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s22

Unit G01
3 Apollo Place
Lane Cove West, NSW 2066
M: s22
Ph: s22
www.medlogicalinnovations.com

MEDLOGICAL
INNOVATIONS

From: TGA Info
To: ECT
Subject: FW: Report of breach of Act or questionable practices - Profocal [SEC=OFFICIAL] CCEMS:02960007361
Date: Wednesday, 2 July 2025 12:20:45 PM

Dear Team
Please find the below email correspondence for your action from: s22 [redacted]. If your area has received this incorrectly, please let us know.
Kindly ensure that any internal correspondence, including this forwarding email, is deleted prior to sending the response.
If you are responding directly to an external enquiry, you are responsible for ensuring that the TGA customer service standards are met.
If your area does not have access to a generic email address, the TCC can send approved responses on your behalf from info@tga.gov.au, provided there is sufficient time for the service standards to be met.
If you have any questions about this email, please contact us.
Kind regards,

s22 [redacted]
TGA Contact Centre
Regulatory Assistance Section
Regulatory Engagement Branch
Phone: 1800 020 653 | Fax: 02 6203 1605
Email: info@tga.gov.au
Therapeutic Goods Administration
Department of Health, Disability and Ageing
PO Box 100
Woden ACT 2606
www.tga.gov.au

---------- Original Message ----------
From: Therapeutic Goods Administration ;
Received: Wed Jul 02 2025 12:13:07 GMT+1000 (Australian Eastern Standard Time)
To: TGA Info ; info-Queue ;
Subject: Report of breach of Act or questionable practices - Profocal

Report of a perceived breach of the Therapeutic Goods Act or questionable practices

relating to therapeutic products

Submitted on Wednesday, July 2, 2025 - 12:12

Contact details

Reporter's name: [redacted]
Reporter's email: [redacted]
Reporter's telepho [redacted]
Reporter's mobile phone number:
Reporter's fax number:

Details of problem

Date problem was encountered: 2025-07-02
Name of product of concern: Profocal
AUST R or AUST L number on product label, if known:
Name of company/person supplying the product: Medlogical Innovations
Address of company/person, if known: 3 Apollo Pl, Lane Cove West NSW
Contact details of company/person, if known (telephone, fax website, etc.):
Email: enquiries@medlogicalinnovations.com
Phone: [redacted]
Details of problem - please be as specific as possible: The only publicly available information about this product says that Profocal is "ProFocal is not approved in any jurisdiction".
I can't find an ARTG certificate relating to this product. The product is promoted to HCPs and patients, it is sold within Australia and patients are paying for the procedure. I would like to know how this product can be available (SAS or Authorized Prescriber), and what, if any, protections are in place to inform patients of the experimental nature of the product.
Do you have a sample of the product or any other supporting material? Yes

From: noreply.ect@heath.gov.au
To: s22 [redacted]
Subject: RE: Report of breach of Act or questionable practices - Profocal [SEC=OFFICIAL] CCEMS:02960007361
Date: Tuesday, 30 September 2025 10:59:24 AM
Attachments: image001.png

Dear s22 [redacted]

Thank you for submitting a report regarding alleged non-compliance of therapeutic goods supply with the *Therapeutic Goods Act 1989*. The reference number for this matter is

RC-062075.

Reports of suspected non-compliance are risk assessed so that we can focus resources on reports that present the highest risk to public health, safety, and confidence in the therapeutic goods regulation. Reports that do not proceed to investigation are used to inform future compliance priorities.

The TGA does not generally release information to the public about specific compliance and enforcement activities, such as current investigations, unless it is necessary or required by the investigative process. We do not release information that might; prejudice a person's right to a fair hearing or legal process; impinge upon the privacy or safety of others involved in the investigation (such as complainants, witnesses and suspects); or prejudice any of our past or future compliance actions.

The TGA does, from time to time, publish compliance actions and outcomes taken under the Therapeutic Goods Act 1989.

If you have any further questions, please do not hesitate to contact us.

Kind regards,

Enforcement Coordination Team

Regulatory Practice and Support Division | Health Products Regulation Group

Regulatory Compliance Branch

Therapeutic Goods Administration

Australian Government Department of Health, Disability and Ageing

PO Box 100, Woden ACT 2606, Australia

---------- Original Message ----------
From: Therapeutic Goods Administration ;
Received: Wed Jul 02 2025 12:13:07 GMT+1000 (Australian Eastern Standard Time)
To: TGA Info ; info-Queue ;
Subject: Report of breach of Act or questionable practices - Profocal

Report of a perceived breach of the Therapeutic Goods Act or questionable practices relating to therapeutic products

Submitted on Wednesday, July 2, 2025 - 12:12

Contact details

Reporter's name: s22 [redacted]
Reporter's email: s22 [redacted]
Reporter's telephone number: s22 [redacted]
Reporter's mobile phone number:
Reporter's fax number:

Details of problem

Date problem was encountered: 2025-07-02
Name of product of concern: Profocal
AUST R or AUST L number on product label, if known:
Name of company/person supplying the product: Medlogical Innovations
Address of company/person, if known: 3 Apollo Pl, Lane Cove West NSW
Contact details of company/person, if known (telephone, fax website, etc.):
Email: enquiries@medlogicalinnovations.com
Phone: s22 [redacted]
Details of problem - please be as specific as possible: The only publicly available information about this product says that Profocal is "ProFocal is not approved in any jurisdiction".
I can't find an ARTG certificate relating to this product. The product is promoted to HCPs and patients, it is sold within Australia and patients are paying for the procedure.
I would like to know how this product can be available (SAS or Authorized Prescriber), and what, if any, protections are in place to inform patients of the experimental nature of the product.
Do you have a sample of the product or any other supporting material? Yes