From: IRIS
To: s22
Subject: RE: DIR 109626 - Request For Information Letter **Response due 22/04/2025** [SEC=OFFICIAL]
Date: Tuesday, 20 May 2025 1:13:24 PM
Attachments: image001.png
image002.png

Dear s22

Thank you for your detailed response on 9 April 2025. I can confirm receipt of this correspondence, and further confirm that DIR 109626 was updated with the correct sponsor details kindly provided by you. All references to s47G have been removed from report DIR 109626 and this report will not be visible in your sponsor portal.

The email you received yesterday (below) was sent to each Australian sponsor for education purposes, to provide clarity for future adverse event reporting requirements. No further action is being requested from you at this time – if you have any questions the next time you are required to report to the TGA, please feel very welcome to reach out via IRIS@health.gov.au, we are only too happy to assist.

Kind regards,

-
s22
-
Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch

Medical Devices and Product Quality Division | Health Products Regulation Group
Therapeutic Goods Administration (TGA)
Australian Government, Department of Health, Disability and Ageing
Email: IRIS@health.gov.au
Phone: s22
Phone:
27 Scherger Drive, Canberra Airport, ACT 2609
PO Box 100, Woden ACT 2606
www.tga.gov.au

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website.
MDIR Technical assistance is available via s22 or email (IRIS@health.gov.au). If you are a sponsor or

manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:
https://apps.tga.gov.au/prod/mdir/udir03.aspx
For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

From: s22 @s47G .com.au>
Sent: Monday, 19 May 2025 2:08 PM
To: IRIS <IRIS@health.gov.au>
Cc: s22 @s47G .com.au>
Subject: RE: DIR 109626 - Request For Information Letter **Response due 22/04/2025** [SEC=OFFICIAL]

Good afternoon,

We received the following e-mail from you. We have emailed a response to your original email on the 9th of April, but attached it again for your reference. Could you please confirm you have received our response?

Thank you.

From: *IRIS <IRIS@health.gov.au>*
Date: *19 May 2025 at 12:35:29 pm AEST*
Subject: Device Incident Report - Final Report Submission [SEC=OFFICIAL]

Dear Sponsor,

We are writing to remind you about the necessity of including an update on the current status of the investigation when submitting the final report. Any final report submitted without this crucial update will not be accepted and will be returned for completion.

As outlined per Therapeutic Goods (Medical Devices) Regulations 2002, 5.8A(2) sponsors are required to submit a final report within 120 days of the initial report. 5.8A(3) of the Regulations specifies the report must:

1. *deal with any updates to that information since that information was given; and*
2. *set out details of the action the person has taken, or the manufacturer of the kind of medical device has taken, to investigate the event or other occurrence concerned; and*
3. *set out details of the action the person has taken, or the manufacturer of the kind of medical device has taken, to alleviate the impact of the event or other occurrence concerned for patients or for users of the kind of medical device; and*
4. *set out details of similar events or occurrences that have occurred in the last 3 years, in relation to the kind of medical device, of which the person is aware.*

It has been noted in the cases where the manufacturer's investigation has not concluded, the information provided by the sponsor in the final report was not sufficient to undertake a risk assessment or found to meet the requirements of a final report regulation 5.8A. The TGA needs to assess whether proportionate action has been undertaken by the manufacturer to address the risks or concerns identified in the report in a timely manner. When you fail to provide information about actions taken, it appears that insufficient action has been undertaken to address the risks within the expected timeframes. Therefore, sponsors should provide information about the current status of the manufacturer's investigation such as the CAPA details or any other actions undertaken since submitting the initial report.

Your cooperation is highly appreciated to ensure that all necessary information is provided in a timely and comprehensive manner.

We are continuing to monitor the compliance of submitted reports against the timeliness and quality requirements, and may take further action in relation to any observed breaches.

Please not that this email is for educational purposes only and no response is required. If you require further clarification in this regard please contact IRIS@health.gov.au.

Regards

s22

Devices Post Market Monitoring Section | Medical Devices Surveillance Branch
Australian Government, Department of Health, Disability and Ageing
Therapeutic Goods Administration

s22

PO Box 100, Woden ACT 2606

www.tga.gov.au

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

Kind regards,

s47G

From: s22

Sent: Wednesday, 9 April 2025 10:39 AM

To: IRIS@health.gov.au

Cc: s22 @s47G .com.au>

Subject: RE: DIR 109626 - Request For Information Letter **Response due 22/04/2025** [SEC=OFFICIAL]

Good morning,

On behalf of s22 please see the attached response.

Kind regards,

s47G

Begin forwarded message:

From: IRIS <IRIS@health.gov.au>

Date: 8 April 2025 at 5:08:10 pm AEST

To: s22 @s47G .com.au>

Subject: DIR 109626 - Request For Information Letter **Response due 22/04/2025 [SEC=OFFICIAL]**

Dear s22

Please see the attached Request For Information Letter for action. **Please note the due date for a response is 22 April 2025.**

Kind regards,

s22

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch
Medical Devices and Product Quality Division | Health Products Regulation Group
Therapeutic Goods Administration (TGA)
Australian Government, Department of Health and Aged Care
Email: IRIS@health.gov.au
Phone: s22
Phone:
27 Scherger Drive, Canberra Airport, ACT 2609
PO Box 100, Woden ACT 2606
www.tga.gov.au

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

please notify the author immediately and delete all copies of this transmission."

Message protected by MailGuard: e-mail anti-virus, anti-spam and content filtering.
https://www.mailguard.com.au/mg

9 April 2024

BY EMAIL IRIS@health.gov.au

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

Dear Administration Officer

DEVICE INCIDENT REPORT DIR 109626 – REF: E25-159914

I refer to your letter dated 8 April 2024 forwarding details of a TGA incident report involving a s47G Quickie Q700M'.

In your letter you have asked that I confirm the ARTG number of the affected device.

I confirm that s47G does not sell any product branded the 'Quickie Q700M'.

I understand however that there is a product supplied by Sunrise Medical Pty Ltd branded the 'Quickie Q700M'. It is possible that this is the product referenced in the TGA incident report.

Whether this is the same product is of course best confirmed with Sunrise Medical Pty Ltd. However, to the extent you may find it helpful, I have enclosed with this letter a list of what I understand to be ARTG registrations held by Sunrise Medical Pty Ltd, and which identifies the 'Quickie Q700M' as being covered by ARTG registrations 100167 and 100375.

I hope you find this information helpful and am happy to assist in any further enquiries you have.

Yours sincerely

s47G

Compliance with Australian Standards - Sunrise Medical

2023

Manual Wheelchairs		
Item	**Applicable Standard**	**ARTG cert**
Quickie 2	AS 3695 & AS 3696	100167
Quickie 2 Lite	AS 3695 & AS 3696	100167
Quickie 5R	AS 3695 & AS 3696	100167
Quickie 7R	AS 3695 & AS 3696	100167
Quickie Q7	AS 3695 & AS 3696	100167
Quickie Access	AS 3695 & AS 3696	100167
Quickie All Court	AS 3695 & AS 3696	100167
Quickie GP	AS 3695	100167
Quickie GP SA	AS 3695	100167
Quickie GPV	AS 3695 & AS 3696	100167
Quickie Iris	AS 3695 & AS 3696	100167
Quickie Nitrum	AS 3695	100167
Quickie QRI	AS 3695 & AS 3696	100167
Quickie QXi	AS 3695 & AS 3696	100167
Quickie SR45	AS 3695 & AS 3696	100167
Quickie Xenon / SA	AS 3695 & AS 3696	100934
Zippie Zone	AS 3695 & AS 3696	100167
RGK Tiga (all models)	AS 3695 & AS 3696	257593
RGK Octane (all models)	AS 3695 & AS 3696	257593
RGK Veypr	AS 3695 & AS 3696	257593
Zippie Xcape	AS 3695 & AS 3696	100167
Zippie Iris Tilt in space	AS 3695 & AS 3696	100167
Zippie TS	AS 3695 & AS 3696	100167
Zippie Voyage Stroller	AS 3695	100167

Powered Wheelchairs		
Item	**Applicable Standard**	**ARTG cert**
Q50 R Carbon	ISO 7176-8:2014	409753
Q100 R	AS 3695	100167 / 100375
Q200 R	AS 3695	100167 / 100375
Quickie Q300 series M, R	AS 3695	100167 / 100375
Quickie Q400 series M, R, F	AS 3695	100167 / 100375
Quickie Q500 series M, R, F	AS 3695	100167 / 100375
Quickie Q700 series M, F, R, Up	AS 3695	100167 / 100375
Quickie Xperience	AS 3695 & AS 3696	100375
Quickie Xplore	AS 3695 & AS 3696	100375
Quickie Xcel	AS 3695 & AS 3696	100375
Zippie ZM-310	AS 3695 & AS 3696	100375
Zippie Q300 M Mini	AS 3695 & AS 3696	100375

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22
s47G
Email: s22 @s47G com.au

File Reference: E25-159914

Dear s22

DEVICE INCIDENT REPORT DIR 109626 - s47G Quickie Q700M Wheelchair - Wheelchair, <specify>

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the TGA database report is attached.

To assist in the evaluation and resolution of this report, could you please provide the information requested below referencing the above DIR number and return it to this office **within 10 working days of the date of this letter and no later than close of business 22/04/2025**.

- Please confirm the ARTG number of the affected device.

Electronic submission of all information is preferred. Please send the requested information to email address: IRIS@health.gov.au

Thank you for your cooperation. If you require further information please contact our team on s22

Yours sincerely,

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

08/04/2025

DIR 109626 - s47G Quickie Q700M Wheelchair - Wheelchair, <specify>

Reporter Reference #: PS1120909

Date of Adverse Event:

Date of Report:
27/03/2025

ARTG #:
109840

Brand Name:
s47G Quickie Q700M Wheelchair - Wheelchair, <specify>

Device Class:
Class 1

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
s47G

Sponsor:
s47G

Contact Name:
s22

Phone:
s22

Reporter:

Confidential: Yes

Clinical Event Information:
s11C

s47G

Module by s47G

Patient Outcome/Consequences:

***** End of DIR 109626 *****

From: IRIS
To: s22
Subject: RE: DIR 109626 - Sponsor User Complete Letter [SEC=OFFICIAL]
Date: Thursday, 8 May 2025 3:49:14 PM
Attachments: image009.png

Hi s22

The model, serial, batch or lot numbers were not provided; I am unfortunately unable to assist with this request.

Kind regards,

s22

-

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch
Therapeutic Goods Administration

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @sunrisemedical.com.au>
Sent: Thursday, 8 May 2025 2:52 PM
To: IRIS <IRIS@health.gov.au>
Cc: s22 @sunrisemedical.com.au>
Subject: RE: DIR 109626 - Sponsor User Complete Letter [SEC=OFFICIAL]

Hi s22

Thank you for providing us with your feedback.

For our record-keeping purposes, would you be able to provide the serial number of the chair?

Regards,

SUNRISE MEDICAL
www.SunriseMedical.com.au

s22
Quality Manager
s22
s22 @sunrisemedical.com.au

From: IRIS <IRIS@health.gov.au>
Sent: Thursday, 8 May 2025 12:33 PM
To: s22 @sunrisemedical.com.au>
Cc: s22 @sunrisemedical.com.au>
Subject: RE: DIR 109626 - Sponsor User Complete Letter [SEC=OFFICIAL]

Good afternoon s22

Thank you for your patience whilst I have followed up with the reporter of DIR 109626.

Consent has been provided to share the attached with Sunrise Medical Pty Ltd for investigation purposes. Please see photographs of the affected wheelchair involved in this adverse event.

I can confirm that s47G has been removed from the Brand Name field of the report to avoid confusion.

Please note the TGA review of this report has now concluded and the TGA is not requesting any further action from you at this time. The TGA will continue to monitor the rate and pattern of occurrence of the reported adverse event and may re-open the file as appropriate.

Kind regards,

s22
-
Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch

Medical Devices and Product Quality Division | Health Products Regulation Group
Therapeutic Goods Administration (TGA)
Australian Government, Department of Health and Aged Care
Email: IRIS@health.gov.au
Phone: s22

Phone: s22
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PO Box 100, Woden ACT 2606
www.tga.gov.au

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https://apps.tga.gov.au/prod/mdir/udir03.aspx
For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

From: s22 @sunrisemedical.com.au>
Sent: Friday, 4 April 2025 4:51 PM
To: IRIS <IRIS@health.gov.au>
Cc: s22 @sunrisemedical.com.au>
Subject: RE: DIR 109626 - Sposnor User Complete Letter [SEC=OFFICIAL]

Dear s22

Thank you for notifying us about the incident potentially involving our wheelchair.

We were unaware of this incident as it was not communicated to us previously. There are a few discrepancies that need clarification:

1. The brand mentioned is s47G which is our competitor and unlikely to sell our chairs.
2. The incident report states, "s47G which is not related to our products.

To confirm if this is indeed our chair, could you please provide the serial number and photos of the chair? Additionally, who can we contact to obtain this information?

Thank you for your assistance.

Regards,

s22
Quality Manager
s22

SUNRISE MEDICAL
www.SunriseMedical.com.au
s22 s22 @sunrisemedical.com.au

#OneSunrise
Join the community!

Begin forwarded message:

From: IRIS <IRIS@health.gov.au>
Date: 4 April 2025 at 4:08:44 pm AEDT
To: s22 @sunrisemedical.com.au>
Subject: DIR 109626 - Sposnor User Complete Letter [SEC=OFFICIAL]

You don't often get email from iris@health.gov.au. Learn why this is important

Dear s22

Please see the attached letter in relation to the Device Incident Report (DIR) that has been submitted to the Therapeutic Goods Administration (TGA) by a healthcare professional.

Kind Regards,

s22

Triage Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch
Medical Devices and Product Quality Division | Health Products Regulation Group
Therapeutic Goods Administration (TGA)
Australian Government, Department of Health and Aged Care

Email: IRIS@health.gov.au
Phone: s22
27 Scherger Drive, Canberra Airport, ACT 2609
PO Box 100, Woden ACT 2606
www.tga.gov.au

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Important: *This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error, please notify the author immediately and delete all copies of this transmission.*

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MDIR Technical assistance is available via s22 or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

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s11C

s11C

s11C

s11C

s11C

Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Australian Medical Device Incident Report Investigation Scheme

s22

Sunrise Medical Pty Ltd
PO Box 6204
Weterill Park NSW 1851
Email: s22 @sunrisemedical.com.au

File Reference: E25-159914
Sent by email

Dear s22

DEVICE INCIDENT REPORT DIR 109626 - ARTG # 100375 - Wheelchair, <specify>

An incident report has been received by the Therapeutic Goods Administration from a healthcare professional/user for the above mentioned medical device and an investigation into the incident is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information. The Therapeutic Goods Administration is not requesting any action from you.

Should you have any further queries concerning this report please contact our team on s22 or send an email to: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Medical Devices Surveillance Branch
Therapeutic Goods Administration

04/04/2025

DIR 109626 - ARTG # 100375 - Wheelchair, <specify>

Reporter Reference #: PS1120909

Date of Adverse Event:

Date of Initial Report:
27/03/2025

ARTG #:
100375

Brand Name:
s47G Quickie Q700M Wheelchair - Wheelchair, <specify>

Device Class:
Class 1

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Sunrise Medical (USA) [42307]

Sponsor:
Sunrise Medical Pty Ltd [21488]
PO Box 6204
Weterill Park NSW 1851

Contact Name: s22

Phone: s22

Fax:

Email:

Reporter:

Confidential: Yes

Clinical Event Information:

s11C

s47G

Module by s47G

Patient Outcome/Consequences:

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Type of Problem (Level 1)	Type of Problem (Level 2)
Material Integrity Problem	Degraded

Cause of Problem (Level 1)	Cause of Problem (Level 2)
No Findings Available	

Outcome of Investigation

Reviewed, for Trending Purposes Only

Summary of Investigation:
The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia, through voluntary cooperation between medical device users, industry and government.

The TGA conducts a review of all adverse event reports received. The outcome may result in the commencement of a formal investigation which could lead to regulatory action such as the recall of the product, advice to users on the safe use of the device, manufacturing improvements and/or design changes. Reports not investigated are used for monitoring and trending analysis. This means that the information is incorporated into an ongoing body of evidence on the current real-world performance and safety profile of the device.

In this instance, no further investigation of the reported event will occur. The TGA will continue to monitor the rate and pattern of occurrence of the reported adverse event and may re-open the file as appropriate.

Thank you for submitting your adverse event report and contributing to the ongoing work of the IRIS scheme.

Date Completed:
04/04/2025

***** End of DIR 109626 *****

From: IRIS
To: s22
Subject: RE: DIR 109626 - Reporter Complete Letter [SEC=OFFICIAL]
Date: Thursday, 8 May 2025 12:44:47 PM
Attachments: image001.png
image003.png
image004.png
image005.png

Thank you s22

Your prompt reply is most appreciated. Thank you for supporting the Medical Device Incident Report Investigation Scheme.

Kind regards,

s22

-

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch
Therapeutic Goods Administration

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From: s22 @act.gov.au>
Sent: Thursday, 8 May 2025 11:47 AM
To: IRIS <IRIS@health.gov.au>
Subject: RE: DIR 109626 - Reporter Complete Letter [SEC=OFFICIAL]

Good morning s22 ,
Yes happy for you to share the photos with Sunrise medical.

s22

ACT Fire & Rescue
T. s22
E. s22 @act.gov.au
E. s22 @act.gov.au
www.esa.act.gov.au

From: IRIS <IRIS@health.gov.au>
Sent: Thursday, 8 May 2025 11:39 AM
To: s22 @act.gov.au>
Subject: RE: DIR 109626 - Reporter Complete Letter [SEC=OFFICIAL]

Good morning s22

Re: Update regarding your report DIR 109626.

The TGA have contacted the sponsor of the wheelchair involved in this event to notify them of the incident and the outcome of the TGA review. Sunrise Medical Pty Ptd have requested that we share copies of the photographs you provided with them for investigation purposes. I have attached the photographs for your convenience of reference.

Would you be happy to provide consent for the TGA to share the photographs with Sunrise Medical Pty Ptd?

I would be most grateful for your response at your earliest convenience via IRIS@health.gov.au

Kind regards,

s22

-
Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch
Therapeutic Goods Administration

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From: IRIS <IRIS@health.gov.au>
Sent: Friday, 4 April 2025 4:03 PM
To: s22 @act.gov.au
Subject: DIR 109626 - Reporter Complete Letter [SEC=OFFICIAL]

Dear s22

Please see the attached letter in relation to the Device Incident Report (DIR) that has been submitted to the Therapeutic Goods Administration (TGA).

Kind Regards,

s22

Triage Team

Medical Device Incident Report Investigation Scheme (IRIS)

Devices Post Market Monitoring | Medical Devices Surveillance Branch

Medical Devices and Product Quality Division | Health Products Regulation Group
Therapeutic Goods Administration (TGA)
Australian Government, Department of Health and Aged Care
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Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22

File Reference: E25-159914

Dear s22

DEVICE INCIDENT REPORT DIR 109626 - s47G Quickie Q700M Wheelchair - Wheelchair, <specify>

An investigation into the incident you reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any questions regarding this report please contact our team on s22 or send an email to: IRIS@health.gov.au

Yours sincerely,
Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

04/04/2025

DIR 109626 - s47G Quickie Q700M Wheelchair - Wheelchair, <specify>

Reporter Reference #: PS1120909

Date of Adverse Event:

Date of Report:
27/03/2025

ARTG #:
100375

Brand Name:
s47G Quickie Q700M Wheelchair - Wheelchair, <specify>

Device Class:
Class 1

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Sunrise Medical (USA)

Sponsor:
Sunrise Medical Pty Ltd
PO Box 6204
Weterill Park NSW 1851

Contact Name:
s22

Phone:
s22

Reporter:

Confidential: Yes

Clinical Event Information:
s11C

s47G

Module by s47G .

Patient Outcome/Consequences:

Investigation Summary:
The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia, through voluntary cooperation between medical device users, industry and government.

The TGA conducts a review of all adverse event reports received. The outcome may result in the commencement of a formal investigation which could lead to regulatory action such as the recall of the product, advice to users on the safe use of the device, manufacturing improvements and/or design changes. Reports not investigated are used for monitoring and trending analysis. This means that the information is incorporated into an ongoing body of evidence on the current real-world performance and safety profile of the device.

In this instance, no further investigation of the reported event will occur. The TGA will continue to monitor the rate and pattern of occurrence of the reported adverse event and may re-open the file as appropriate.

Thank you for submitting your adverse event report and contributing to the ongoing work of the IRIS scheme.

Date Completed:
04/04/2025

***** End of DIR 109626 *****

From: Product Safety Assessment
To: IRIS
Cc: s22 ; Product Safety Assessment
Subject: RE: DIR 109626 - PS1120909 – Unsafe product report – ACCC to TGA [SEC=OFFICIAL]
Date: Wednesday, 16 April 2025 10:25:12 AM
Attachments: image001.png
image003.png
image004.png
image006.png

OFFICIAL

Good morning s22

Unfortunately, we cannot provide consent to share the photos with the sponsor of the affected device.

To gain this consent, the TGA will have to contact the consumer.

Kind regards

---

s22

From: IRIS <IRIS@health.gov.au>
Sent: Monday, 14 April 2025 3:29 PM
To: Product Safety Assessment <ProductSafetyAssessment@accc.gov.au>
Cc: s22 @accc.gov.au>; s22 @accc.gov.au>
Subject: RE: DIR 109626 - PS1120909 – Unsafe product report – ACCC to TGA [SEC=OFFICIAL]

Good afternoon s22

Thank you for providing the information below.

Can you please provide consent for the TGA to share the photos provided with the Sponsor of the affected device.

If you have any questions, or if we can be of assistance please do not hesitate to contact us.

Kind regards,

s22

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch

Medical Devices and Product Quality Division | Health Products Regulation Group
Therapeutic Goods Administration (TGA)

Australian Government, Department of Health and Aged Care
Email: IRIS@health.gov.au
Phone: s22
Phone:
Post: 27 Scherger Drive, Canberra Airport, ACT 2609
Courier: 1 Tindal Lane, Canberra Airport, ACT 2609
www.tga.gov.au

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website.
MDIR Technical assistance is available via s22 or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:
https://apps.tga.gov.au/prod/mdir/udir03.aspx
For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

From: Product Safety Assessment <ProductSafetyAssessment@accc.gov.au>
Sent: Monday, 14 April 2025 11:34 AM
To: IRIS <IRIS@health.gov.au>
Cc: Product Safety Assessment <ProductSafetyAssessment@accc.gov.au>; s22 @accc.gov.au>; s22 @accc.gov.au>

Subject: RE: DIR 109626 - PS1120909 – Unsafe product report – ACCC to TGA [SEC=OFFICIAL]

OFFICIAL

Good morning s22

Thank you for your email.

Unfortunately, we do not have information regarding the serial number or model number of the product. However, if it is helpful, I have **attached** photographs of the wheelchair in question provided to us by the complainant.

The complainant has given consent for their details to be disclosed to other agencies.

If you have any further questions, please feel free to contact me.

Kind regards
s22

---

s22

From: Product safety <Productsafety@accc.gov.au>
Sent: Thursday, 10 April 2025 9:27 AM
To: Product Safety Assessment <ProductSafetyAssessment@accc.gov.au>
Subject: FW: DIR 109626 - PS1120909 – Unsafe product report – ACCC to TGA [SEC=OFFICIAL]

From: IRIS <IRIS@health.gov.au>
Sent: Thursday, April 10, 2025 9:24:40 AM (UTC+10:00) Canberra, Melbourne, Sydney
To: productsafetyassessment@accc.gov.au. <productsafetyassessment@accc.gov.au.>
Cc: Product safety <Productsafety@accc.gov.au>
Subject: RE: DIR 109626 - PS1120909 – Unsafe product report – ACCC to TGA [SEC=OFFICIAL]

Good morning Research and Assessment team,

Thank you for referring this adverse event report to the TGA.

The IRIS team have commenced a review of this report, and a discrepancy was noted in the description of the affected medical device. The product name "s47G Quickie Q700M Wheelchair" appears to relate to two different sponsors.

To assist with identifying the specific wheelchair, are you able to please provide the serial number, model number and any photographs you may have available?

Has the original reporter of the event given consent to be contacted by TGA directly?

We look forward to hearing back from you at your earliest convenience via IRIS@health.gov.au

Kind regards,

s22

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch

Medical Devices and Product Quality Division | Health Products Regulation Group
Therapeutic Goods Administration (TGA)
Australian Government, Department of Health and Aged Care
Email: IRIS@health.gov.au
Phone: s22
Phone:
27 Scherger Drive, Canberra Airport, ACT 2609
PO Box 100, Woden ACT 2606
www.tga.gov.au

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website.
MDIR Technical assistance is available via s22 or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:
https://apps.tga.gov.au/prod/mdir/udir03.aspx
For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

From: Product safety <Productsafety@accc.gov.au>
Sent: Thursday, 27 March 2025 11:02 AM
To: ADR Reports <ADR.Reports@health.gov.au>
Subject: PS1120909 – Unsafe product report – ACCC to TGA [SEC=OFFICIAL]

Dear TGA

Please find attached a report of an alleged unsafe product submitted to the Australian Competition and Consumer Commission (ACCC). We are referring this report to you as it appears to fall within the jurisdiction of your agency.

The complainant has consented to the ACCC sharing the information contained within the report and should be treated with the same level of confidentiality afforded it under your privacy policy.

We would appreciate notification if the information provided in the report leads to any action by your agency.

If you require further information, please contact the Research and Assessment team at productsafetyassessment@accc.gov.au.

Research and Assessment | Risk Assessment and Operations Branch
Australian Competition & Consumer Commission
Consumer Product Safety
Ngunnawal country
23 Marcus Clarke St Canberra
GPO Box 3131, Canberra ACT 2601
productsafety.gov.au

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

From: ADR Reports
To: IRIS
Subject: FW: PS1120909 – Unsafe product report – ACCC to TGA [SEC=OFFICIAL]
Date: Thursday, 27 March 2025 11:22:05 AM
Attachments: PS1120909_details.xlsx
Complaint.pdf

Good morning,

Would this report be relevant for your section?

Kind Regards

s22
Departmental Officer
Adverse Event & Medicine Defect Section
Pharmacovigilance Branch
Email: adr.reports@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

Follow on: Twitter | Facebook | Pinterest | YouTube
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.

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We would appreciate notification if the information provided in the report leads to any action by your agency.

If you require further information, please contact the Research and Assessment team at productsafetyassessment@accc.gov.au.

Research and Assessment | Risk Assessment and Operations Branch
Australian Competition & Consumer Commission
Consumer Product Safety
Ngunnawal country
23 Marcus Clarke St Canberra
GPO Box 3131, Canberra ACT 2601
productsafety.gov.au

Unsafe Product Report Details

Product Safety Number PS1120909

Report Details	
Report number	PS1120909
Web Reference Number	
Date submitted	
Consent to disclose	Yes

Primary Contact Details	
Anonymous	False
Title	s22
First name	
Last name	
Business Phone	
Home Phone	
Mobile Phone	
Email address	s22
Address line 1	
Address line 2	
Address line 3	
City/suburb	s22
State	
Postcode	
Country	Australia

Supplier name	
ABN	
Supplier phone	
Supplier phone 2	
Supplier email	
Supplier website	
Supplier address 1	
Supplier address 2	
Supplier address 3	
Supplier suburb	
Supplier state	
Supplier postcode	
Supplier country	
Business Organisation	Not Applicable / N/A / Unknown / Anonymous

Product	
Name	s47G Quickie Q700M Wheelchair
Brand	s47G Quickie Q700M
Description	
Product Category	Mobility and accessibility aids
Country of manufacture	
Country of origin	
Recommended retail price	
Approx lifespan of product	

How was the product obtained?		
Purchase date	24/03/2025	
In store	○	
Online	○	
Other	◉	s11C Unknown where the product was purchased.
Contacted Supplier?	○	
Outcome of contact with supplier		
Other action taken	Nil	

Description

Describe What Happened

s11C

s47G

Attachment(s)

Attachment Name	Attachment Type	iManage No	iManage Processing Status

Unsafe Product Report Details

Product Safety Number PS1120909

Report Details

Report number	Web Reference Number	Date submitted	Consent to disclose
PS1120909			Yes

Primary Contact Details

Anonymous	Title	First name	Last name	Business Phone	Home Phone	Mobile Phone	Email address	Address line 1	Address line 2	Address line 3	City/suburb	State	Postcode	Country
No	s22													Australia

Supplier Details

Supplier name	ABN	Supplier phone	Supplier phone 2	Supplier email	Supplier website	Supplier address 1	Supplier address 2	Supplier address 3	Supplier suburb	Supplier state	Supplier postcode	Supplier country	Business Organisation
													Not Applicable / N/A / Unknown / Anonymous

Product

Name	Brand	Description	Product Category	Country of manufacture	Country of origin	Recommended retail price	Approx lifespan of product
s47G Quickie Q700M Wheelchair	s47G Quickie Q700M		Mobility and accessibility aids				

How was the product obtained?

Purchase date	In store	Online	Other	Purchased - Other	Contacted Supplier?	Outcome of contact with supplier	Other action taken
24/03/2025	No	No	Yes	s11C	No		Nil

Description

Describe What Happened

s11C

s47G

Attachment(s)

Attachment Name	Attachment Type	iManage No	iManage Processing Status

Form Date: 28/03/2025
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 48 - ID : 612681

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
109626	E25-159914	PS1120909	Final

ARTG: 100375

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed			27/03/2025
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
27/03/2025	28/03/2025		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
08/04/2025			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Other		Trend data only	

Event Description for Website Publication:

Burnt out wire.

Clinical Event Information:

s11C

s47G

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Contact Email:

s22 @act.gov.au

Recorded Problems Observed

Recorded Problems Observed:

Material Integrity Problem -> Degraded ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Others -> Insufficient Information ->

Health Impact

Recorded Health Impacts:

Insufficient Information -> ->

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

Mobility and accessibility aids

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:

Reporter #:

Preferred Contact Method:

Reporter Title: s22

First Name: s22

Surname: s22

Position:

Company/Institution:

Address 1: s22

Address 2:

Town/Suburb: s22

State: s22

Country:

Postcode: s22

Phone: s22

Fax:

Mobile:

Email: s22 @act.gov.au

Last External Submission By:

Initial Reporter Section

As Above?: Yes

If No, fill out the following:

Initial Reporter Confidential: Yes

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG: 100375

Device ARTG #: 100375

Therapeutic Licence Type: Medical Device

Product Licence Category:

Device Class:

GMDN / UMDN Code:

GMDN / UMDN Text:

Included	Class 1	14449	Wheelchair,
Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
Quickie Q700M Wheelchair - Wheelchair,	Quickie Q700M Wheelchair - Wheelchair,	Reuse of Reusable	
Model #:	Serial #:	Batch #:	Lot #:
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	24/03/2004	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Sunrise Medical (USA)		42307	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Acknowledgement Letter Section

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Device not returned	Team C (IIa, I and IVD 1-4)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date: 01/04/2025	Severity: 1 - No harm has been reported to occur	Incidents in the last 12 months:	Manufacturer analysis: No	Assessor: s22	Manufacturer documentation: Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action: Yes	ESTIMATED LEVEL OF INVESTIGATION: Level 1 Investigation (to complete screening)	FINAL LEVEL OF INVESTIGATION: Screening only	Injured Party: Not Applicable	Device Recalls: 0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL: device not retuned.		Found Prior To Use: No	Is AE covered by current recall:
Incidents Worldwide:	Number of potential contributing factors: No			Reusable: Yes	Similar events (past 6 months): 0 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY: Routine	FINAL LEVEL OF PRIORITY: Routine		3 or more events - batch/model:
Products supplied last 24 months:	Number of potential sensitivities: No	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment: I undertook an internet search (e.g., Google)	Final Risk Assessment: Yes			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		

Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
	3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
	3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
21488	Sunrise Medical Pty Ltd		21488
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO BOX 6204		Wetherill Park DC
State:	Postcode:	Phone:	Fax:
NSW	1851	s22	
Email:			
s22 @sunrisemedical.com.au			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Details of Similar Events:
Additional Details (use for tables):	CAPA# Reference:

Risk Assessment

Frequency:	Severity:
Rating:	

Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:	
Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Closed 01/04/2025

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus

Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source

Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		04/04/2025				04/04/2025 - D25-1435277
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		04/04/2025		04/04/2025	04/04/2025 - Sunrise Medical Pty Ltd responded seeking additional information D25-1436499. --- 08/05/2025 - Sunrise Medical Pty Ltd provided photos with Initial Reporter's consent D25-1961996. Sponsor details updated and DIR re-closed.	04/04/2025 - D25-1435345
☐		Sponsor Routine Correspondence	Sponsor Request for Information – email or letter/informal		08/04/2025	22/04/2025	09/04/2025	10/04/2025 - s47G responded stating this is not their product D25-1518750.	08/04/2025 - RFI seeking ARTG confirmation sent to updated sponsor D25-1489325.
☐		Reporter Routine Correspondence	Reporter Request for Information – email		10/04/2025	24/04/2025	22/04/2025	14/04/2024 - D25-1591285 Response with photos received. ----------	10/04/2025 - email sent to ACCC requesting additional info to identify device D25-1519742. Note: the initial reporter was sent the User

								-22/04/2025 - Email received not providing consent. We will need to contact consumer for approval. We do not have consumer information. D25-1700634	Complete Letter 14/04/2025 - Email sent to Reporter to gain consent to share photos with Sponsor. D25-1593667
☐		Reporter Routine Correspondence	Email to Reporter		08/05/2025	22/05/2025	08/05/2025	08/05/2025 - Consent provided D25-1961102.	08/05/2025 - email sent to initial reporter requesting consent to share photos with the sponsor (changed back to Sunrise Medical Pty Ltd) to provide confirmation of the identification of device D25-1960368.

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Material Integrity Problem	Degraded		

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3
Others	Insufficient Information	

Health Impact

Details

Level 1	Level 2	Level 3
Insufficient Information		

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			

Investigation Conclusion

Conclusion Details

Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested
Cause Not Established		

Investigation Outcomes

Outcome Details

Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested
Reviewed, for Trending Purposes Only		

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:
			No

Investigator's Notes:

Summary Findings:

The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia, through voluntary cooperation between medical device users, industry and government.

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In this instance, no further investigation of the reported event will occur. The TGA will continue to monitor the rate and pattern of occurrence of the reported adverse event and may re-open the file as appropriate.

Thank you for submitting your adverse event report and contributing to the ongoing work of the IRIS scheme.

Recall Number:

Completion Report Generation

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
[New]	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
[New]	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		...– ACCC to TGA [SEC=OFFICIAL] - Email 14-04-2025 11	17476	Form	

Flow Details : DIR-REQ - Device Incident Request : 474544

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
474544	DIR-REQ		Closed	s22	OPR Administration User	08/05/2025	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	08/05/2025 13:00:35	
Comment		

Created By s22 - 28/03/2025 14:19:24

Template Revision Released by Theta Technologies on 02/05/2025 08:41:08

From: s22
To: IRIS
Subject: RE: DIR 109626 [SEC=OFFICIAL]
Date: Wednesday, 2 July 2025 2:15:04 PM
Attachments: image005.png
image006.png
image007.png
image930317.png

Thanks s22

Appreciate the quick response. I had hoped that you would be able to release information about this DIR earlier on request so we can get on with our investigation, but if that is not possible I will wait for the DAEN to be updated.

Kind regards,

s22, Group Engineering Manager
K Care Healthcare Solutions

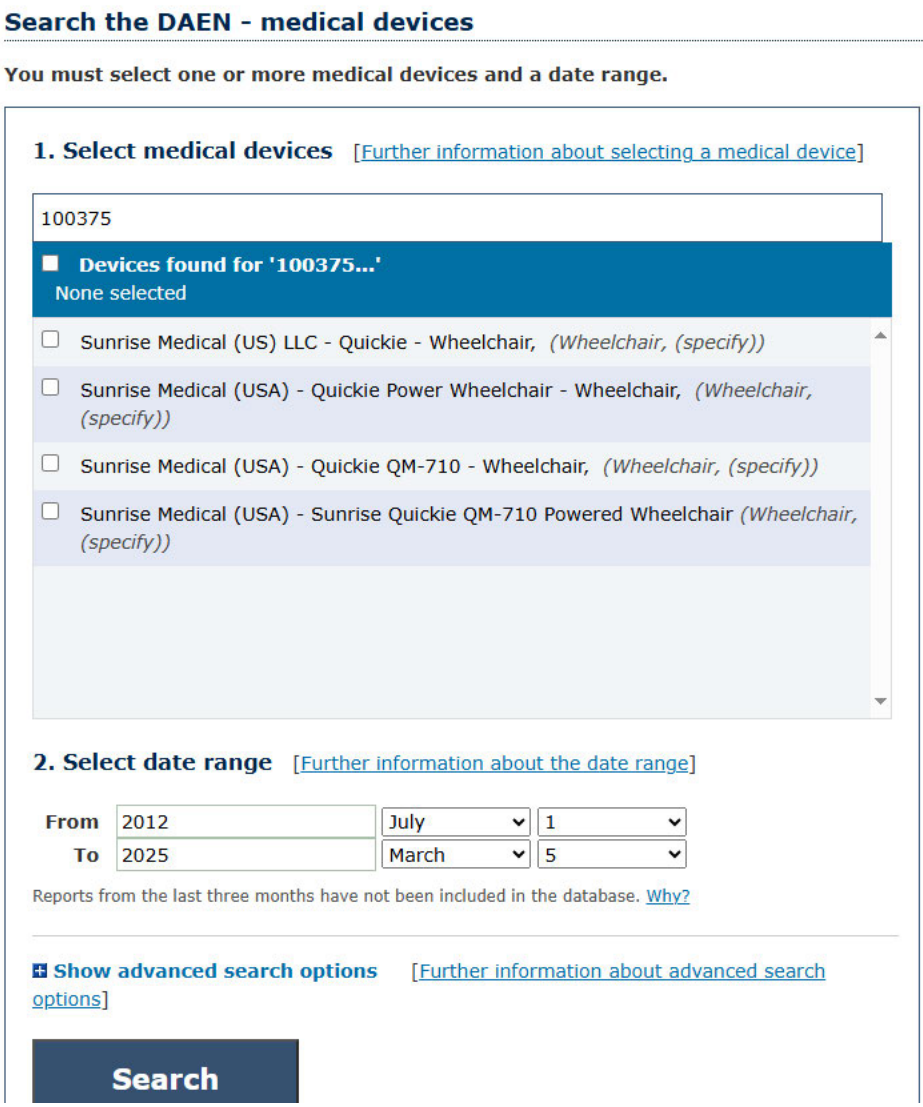
Tel: 1300 783 783 | **Fax:** 1300 784 784 | **Mobile:** s22
Email: s22 @kcare.com.au | **Web:** www.kcare.com.au
Address: 12/9-11 Yazaki Way, Carrum Downs, VIC, 3201

From: IRIS <IRIS@health.gov.au>
Sent: Wednesday, 2 July 2025 2:11 PM
To: s22 @kcare.com.au>
Subject: RE: DIR 109626 [SEC=OFFICIAL]

Good afternoon s22

Thank you for your enquiry.

A search of the Database of Adverse Event Notifications has yielded the following results.



As stated on the website, reports from the last three months are not included in the published database. We expect that the report you mention DIR 109626 will be publicly available soon, please check back for future updates.

Kind regards,

s22 – Administration Officer
Device Support Team – Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch
Medical Devices and Product Quality Division | Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing
T: s22
E: IRIS@health.gov.au

This email comes to you from Ngarigo Country
Location: Gulgana
PO Box 100, Woden ACT 2606, Australia

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website.
MDIR Technical assistance is available via s22 or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).
Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via: https://apps.tga.gov.au/prod/mdir/udir03.aspx
For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

From: s22 @kcare.com.au>
Sent: Tuesday, 1 July 2025 2:18 PM
To: IRIS <IRIS@health.gov.au>
Subject: DIR 109626

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.

Hi There,

I have been asked to investigate an issue with a Sunrise Medical Q700M power wheelchair that has apparently been reported to the TGA under DIR 109626. I have not been able to find this incident by searching in the DAEN and wonder if you are able to share with me any information about this incident.

Kind regards,

s22 Group Engineering Manager
K Care Healthcare Solutions

Tel: 1300 783 783 | **Fax:** 1300 784 784 | **Mobile:** s22
Email: s22 @kcare.com.au | **Web:** www.kcare.com.au
Address: 12/9-11 Yazaki Way, Carrum Downs, VIC, 3201