

From: s22 [redacted] on behalf of [eBS Helpdesk](#)
To: s22 [redacted] [@safeobstetrics.com](mailto:s22@safeobstetrics.com)
Subject: Safe Obstetric Systems Pty Ltd (63633) - TOS ARTG 225818 [SEC=UNCLASSIFIED]
Date: Monday, 14 December 2015 9:42:23 AM
Attachments: [TGA v2 Transfer of sponsor form 11Dec15.PDF](#)

Dear s22 [redacted],

I can confirm the notification to transfer ARTG 225818 from Mercer Medical Australia (Client ID 60923) to Safe Obstetric Systems Pty Ltd (Client ID 63633) has been processed today.

You will receive confirmation letters in the next two weeks.

Kind regards,

s22 [redacted]

TBS Helpdesk
Product Billing and Industry Assistance
Regulatory Services and Improvement Branch
Therapeutic Goods Administration (TGA)

Tel: 1800 010 624
+61 2 6232 8888
Fax: +61 2 6232 8581
E-Mail: ebs@tga.gov.au
Postal: PO Box 100
WODEN ACT 2606
AUSTRALIA

From: s22 [redacted] SOSA [mailto:s22 [redacted]@safeobstetrics.com]
Sent: Friday, 11 December 2015 5:48 PM
To: eBS Helpdesk
Subject: V2 update transfer of sponsor form TGA Business Services User Account - Action Required

Hello s22 [redacted], I have logged onto administrator dashboard and check that all is correct regarding contact details. Please find attached updated transfer of sponsor form. Hope that this can now progress to new certificate. Please let me know when finalised. Kind regards

s22 [redacted] / Safe Obstetrics Systems AU/NZ / Director Sales / s22 [redacted]

From: eBS Helpdesk [mailto:eBS@tga.gov.au]
Sent: Friday, 11 December 2015 3:40 PM
To: s22 [redacted] [@safeobstetrics.com](mailto:s22@safeobstetrics.com)>
Subject: TGA Business Services User Account - Action Required

Dear s22 [redacted],

Your account to access TGA Business Services has been created or modified and may require action.

1 - Are you a new user requiring access to TGA Business Services or are you an existing user who has requested a password reset?

[I want to set my password.](#)

This must be completed within 24hrs of receiving this email, otherwise the link expires.

If this request was made by mistake then please disregard this email.

2 - Are you an existing user who has had a change of system role?

This email is for information only and there is no action required on your part. In the first instance questions about your system access should be directed to the TGA Business Services Administrator within your Organisation.

Regards
TGA Business Services Administration Team

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information and has been sent in accordance with the TGA security policy.

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."

ATTN



Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

1/3 pages
RESULT
FRI 11 DEC

This form, when completed, will be classified as 'For official use only'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<<https://www.tga.gov.au/treatment-information-provided-tga>>.

Notification: Transfer of Sponsorship following death, bankruptcy or winding up



- This form is to be completed by the new sponsor (e.g. lawyer, executor, liquidator)
- There is **no fee** required for this notification.
- Please ensure you read Changes of sponsorship to therapeutic goods prior to completing and submitting this form.

Send completed forms to the eBS Helpdesk at:

Email: sponsortransfers@tga.gov.au

Fax: 02 6232 8581

Post: eBS helpdesk, TGA, PO Box 100, Woden ACT 2606, Australia

Section 1 - Details of notification

Type of notification

Where the former sponsor was an individual:

Death of sponsor

Bankruptcy of sponsor

Where the former sponsor was a company:

Liquidation (winding up) of sponsor

Date of event:

Name of former sponsor	Mercer Medical Australia
Client ID	60923
Name of new sponsor	Safe Obstetric Systems Pty Ltd

Section 2 - Declarations



Please note: Under section 137.1 of the *Criminal Code Act 1995*, it is an offence to knowingly provide information to a Commonwealth entity that is false or misleading in a material particular, or to omit any information without which the information is misleading in a material particular.

Penalty: 12 months imprisonment

I declare I am:

the new sponsor (acquirer)

OR

authorised to make this declaration on behalf of the new sponsor

I declare that the information I have provided above is true and correct.

Full name:	s22 [REDACTED]		
Position:*	Director Sales Australia / new Zealand	Email:	s22 [REDACTED]@safeobstetrics.com
Telephone:	1800 834 961	Facsimile:	
Signature	s22 [REDACTED]	Date:	10 December 2015

**e.g. managing director or regulatory affairs officer of new sponsor; agent of the new sponsor*

Please note: We may be request more information before making the changes to the ARTG entries. We will usually update the relevant entries within 10 working days of receiving the notification.

From: s22
To: [Devices](#)
Subject: RE: RENEWAL - Mercer Medical ID# 225818 [SEC=UNCLASSIFIED]
Date: Monday, 13 July 2015 7:47:46 PM
Attachments: [image001.png](#)

Thank you s22 ... all clear. Regards s22

From: s22 [mailto:s22@tga.gov.au] **On Behalf Of** Devices
Sent: Monday, July 13, 2015 4:37 PM
To: s22
Subject: RE: RENEWAL - Mercer Medical ID# 225818 [SEC=UNCLASSIFIED]

Dear s22,

I have spoken with the Finance team and they have advised that once the invoice for the annual charge has been sent, you will be given around a month in order to pay the charge in order for the ARTG entry to remain current.

From approximately 1st September, if the annual charge has not been paid then the ARTG entry will be cancelled.

I trust this answers your queries.

Yours sincerely

s22

Medical Devices Information Unit
Devices Authorisation Branch
Therapeutic Goods Administration

Phone: 1 800 141 144
Fax: 02 6232 8785
Email: devices@tga.gov.au

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



From: s22 [mailto:s22@mercerproducts.com.au]
Sent: Monday, 13 July 2015 3:38 PM
To: Devices
Cc: TGA Info
Subject: RE: RENEWAL - Mercer Medical ID# 225818 [SEC=UNCLASSIFIED]

Thanks you s22 I have updated my PW and accessed TGA site. QUESTION – our attached certificate start date was 16 July14..... will there be any issues with the lag in re-registration?

Regards s22

From: s22 [redacted] @tga.gov.au] On Behalf Of Devices
Sent: Monday, July 13, 2015 3:22 PM
To: s22 [redacted]
Cc: TGA Info
Subject: FW: RENEWAL - Mercer Medical ID# 225818 [SEC=UNCLASSIFIED]

Dear s22 [redacted],

Thank you for your query to the TGA.

I have investigated with the Finance team and can advise that the invoice for the annual charge will be sent to you on or around 23rd July.

If you are unable to access your TGA Business Services login, please contact the TGA Business Services helpdesk on 1800 010 624 or email ebs@tga.gov.au.

I trust this information is of assistance.

Yours sincerely

s22 [redacted]

Medical Devices Information Unit
Devices Authorisation Branch
Therapeutic Goods Administration

Phone: 1 800 141 144
Fax: 02 6232 8785
Email: devices@tga.gov.au

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



From: TGA Info
Sent: Monday, 13 July 2015 2:41 PM
To: Devices
Subject: FW: RENEWAL - Mercer Medical ID# 225818 [SEC=UNCLASSIFIED]

Good Afternoon Devices

Please find attached an email for your follow up and response - if your area is not the appropriate area to respond to this email please let us know.

If you are responding directly to an external enquiry, you are responsible for ensuring that the [TGA customer service standards](#) are met.

Please ensure that any internal correspondence is deleted prior to sending the response.

If your area does not have access to a generic email address, the PCT can send approved responses on your behalf from info@tga.gov.au, provided there is sufficient time for the service standards to be met.

Yours sincerely

Regulatory Assistance Section
Regulatory Services and Improvement Branch

Phone: 1800 020 653 Fax: 02 6203 1605
Email: info@tga.gov.au

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

From: s22 [redacted] [@mercercorporation.com.au](mailto:s22@mercercorporation.com.au)
Sent: Monday, 13 July 2015 12:52 PM
To: TGA Info
Subject: RENEWAL - Mercer Medical ID# 225818

Could you please advise that Mercer has been mailed/emailed to re-register the attached certificate.

- Confirm date sent
- Confirm email / delivery address
- Confirm contact name.

I am unable to access your site under my PW/UN.

Regards

s22 [redacted]
Australia Manager
MERCER MEDICAL

s22 [redacted]
P 1800 834 961



16 Blivest St. Oxley, 4075 Qld. Australia

www.mercermedical.com.au

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Medical Device Application

ARTG No : 225818

Class 1 Sterile Status: Approved

Application Change history

Classification appears acceptable under rule 3.1(2a). Annex V certificate scope covers device under 'sterile foetal pillow'. (s22 [REDACTED] 15/07/2014)

Application Progress Date

Date received: 24/06/2014

Review Information

Review flag:

Auto review required: No

Device Product Characteristics

Is the device, or any form of the device, supplied sterile: Yes

Is the device intended to be invasive:

Is the device, or any form of the device, intended for single use: Yes

Is the device an active device:

Does the device contain material or ingredients of microbial origin:

Does the device contain material or ingredients of recombinant origin:

Does the device contain material or ingredients manufactured or formulated using a genetically modified organism:

Does the device contain material or ingredients of Human Origin:

Does the device consist of: s47 [REDACTED]

Does the device contain material or ingredients of Animal Origin rendered non-viable:

Is the device medicated:

Does the product contain a medicine that is supplied separately in the Australian Market:

Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device:

Application Summary

Application ID: DV-2014-DA-10479-1

Submission ID: DA-2014-04261-1

Sponsor's own reference: Safe Obstetrics Fetal Pillow

Application for: Medical Device - Included

Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)? Yes No

Will you be applying for listing of this product on the Prosthesis List? Yes No

Will you be applying for listing of this product on the Co-dependent or hybrid technology application list? Yes No

Sponsor name: Mercer Medical Australia

Sponsor ID: 60923

Agent name: GSE Pty Ltd

Contact details: s22

Contact email: s22@gsenderprises.com.au

Is this application supported by EU MDR/IVDR certification?

Manufacturer Information

Manufacturer's evidence: DV-2014-MC-10047-1 :Safe Obstetric Systems Annex V [Goto](#)

Manufacturer name: Safe Obstetric Systems Ltd (United Kingdom)[58912]

Certificate issued under: Council Directive 93/42/EEC (MDD)

Conformity assessment procedure: Schedule 3 Part 4 (Annex V)

Assessment body: SGS United Kingdom Limited [0120]

GMDN code: Foetal membrane manipulator[47978]

GMDN description: A sterile device used to atraumatically mechanically push and position an exposed or prolapsed foetal membrane secondary to an incompetent cervix back through the cervical canal and into the uterus to facilitate the surgical placement of a cervical cerclage in order to prolong pregnancy to a successful live delivery. The device consists of a catheter with a tipless inflatable balloon with a through passage allowing the introduction of injected sterile saline and connectors to accommodate inflation of the balloon and the connection of a syringe; the syringe may be included with the device. This is a single-use device.

Intended purpose: An inflatable 'pillow' that is inserted via the vagina, used to cushion and raise the head of the foetus during a caesarian section following unsuccessful vaginal birth. The cushion is inflated using a manual syringe.

Device Category Terms

Attached Documentation

History

16/07/2014 8:01:47 AM Approved.

Review Completed - Accepted, 16/07/2014)

Record	Date	
Fee:	Date Paid:	30/06/2014
	Date Decision:	15/07/2014

Start Dates	Finish Dates		Working Days	
Application Received	24/06/2014	Payment Received	30/06/2014	4
		Total Working Days		4



EC Certificate Production Quality Assurance System: Certificate
GB12/87076

The management system of

Safe Obstetric Systems Ltd

Berkeley Townsend, Hunter House, 150 Hutton Road,
Shenfield, CM15 8NL, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

Restricted to the aspects of manufacture concerned with securing and
maintaining sterile conditions.

For the following products

Sterile Fetal Pillow

This certificate is valid from 23 November 2012 until 22 July 2015 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 22 July 2013
Issue 1. Certified since 30 November 2010

Certification is based on reports numbered GB/PC 229262

Authorised by



SGS United Kingdom Ltd, Notified Body 0120

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SGS CE 18 0811

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