Guide for Final FSCA Report Submission

OSCAR | **O**nline **S**afety, **C**ompliance **A**pplication and **R**egistration System
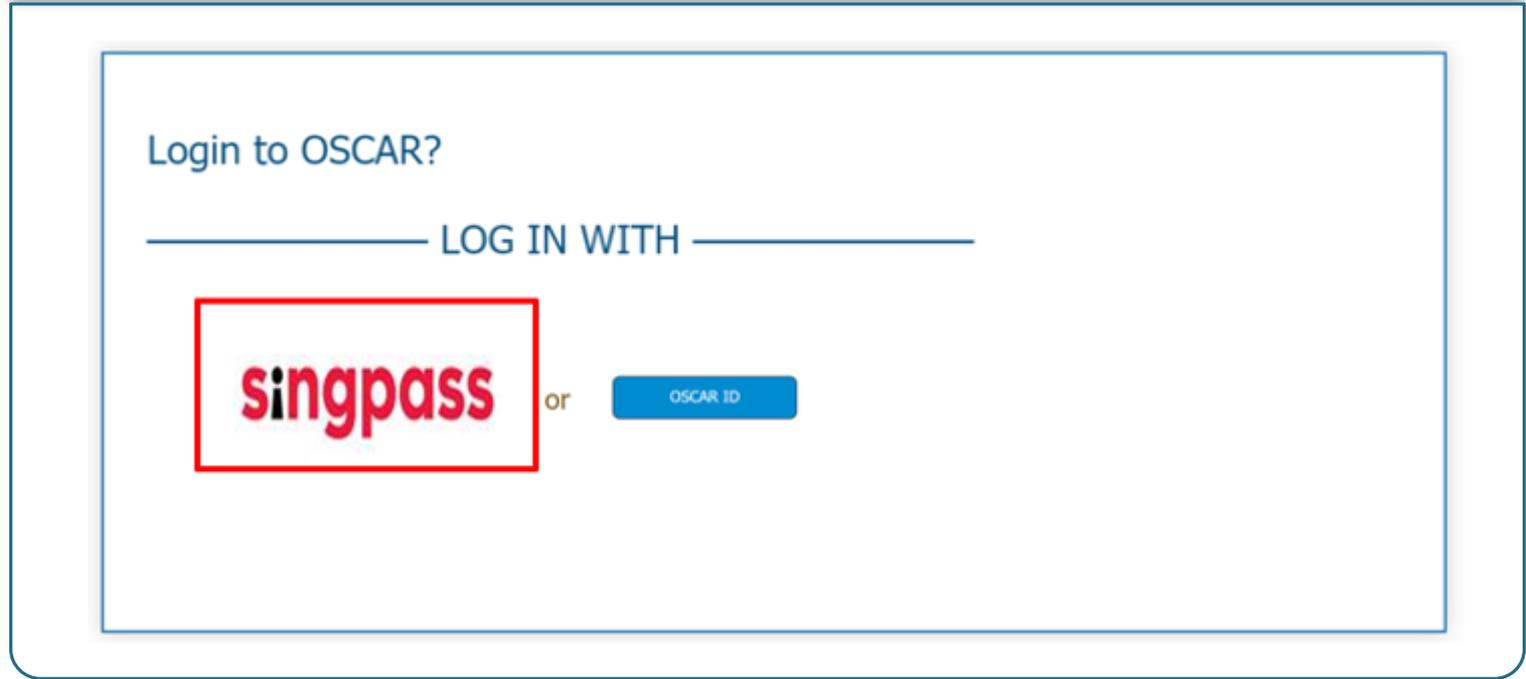
HSA
Health Sciences Authority

IMPORTANT NOTES

❑ For companies accessing OSCAR for the first time, please refer to the User Account Creation Guide for instructions on how to access OSCAR and create accounts for new users.

❑ If you do not have an OSCAR account, please contact your company's OSCAR Administrator(s) for creation of your OSCAR user account.

❑ For new FSCA reporting, please refer to the Guide for New FSCA Report Submission.
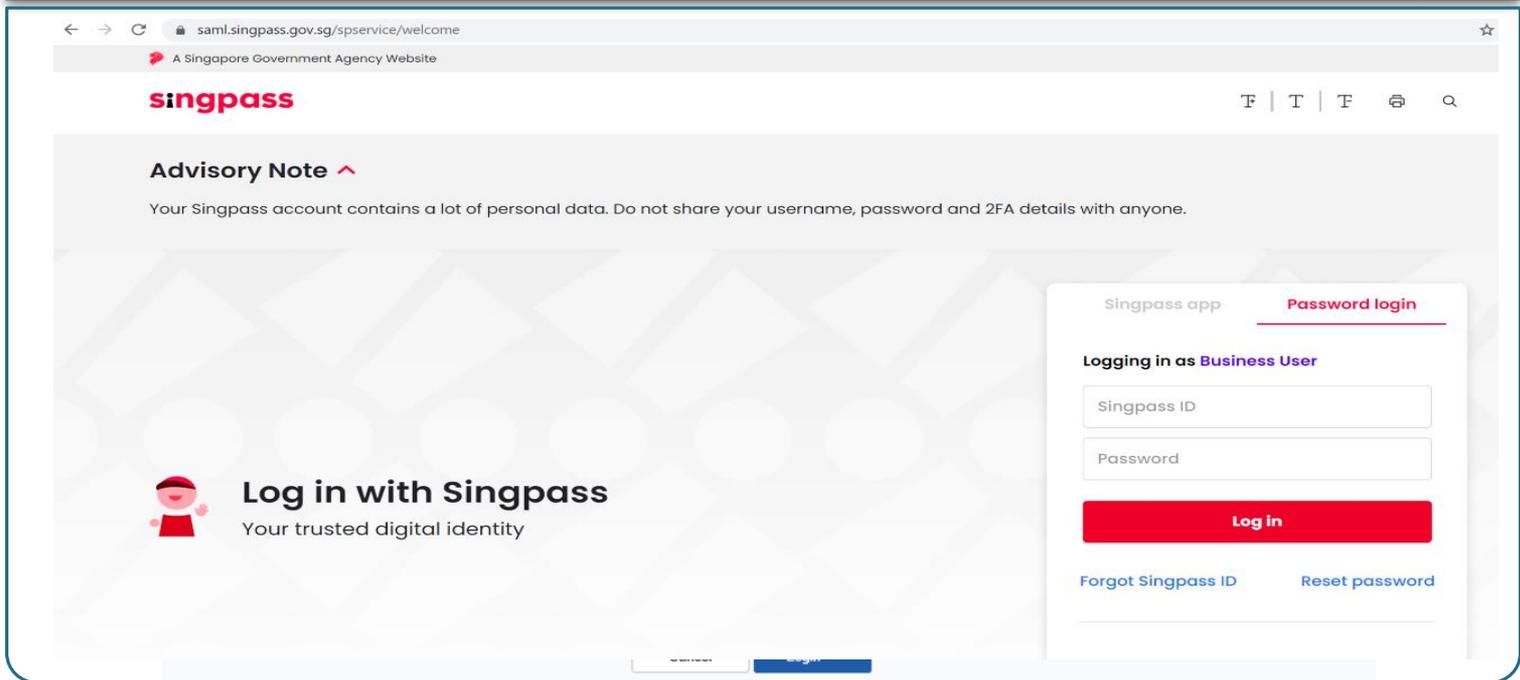
Guide For Final FSCA Report Submission

| Login | Create Final FSCA Report | Complete FSCA Report | Verify and Submit |

Click on the Singpass icon as shown below.

Login to OSCAR?

———————— LOG IN WITH ————————

singpass or [OSCAR ID]

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Enter the details and click on log in.

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Login → **Create Final FSCA Report** → **Complete FSCA Report** → **Verify and Submit**

Complete 2FA verification.

Log Out 👤

You have not completed your 2FA setup. 2FA is required to access e-Service.

Log in **SingPass** to register for a OneKey Token and set up your 2FA.

If you are residing overseas and have not updated your address with Immigration & Checkpoints Authority of Singapore (ICA), click **here** for more details.

You are given a **9999**-day grace period to set up your 2FA. From **29/05/2044** onwards, you will **not be able** to access this e-service and others involving sensitive data, until you have set up your 2FA.

Continue

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Login → **Create Final FSCA Report** → Complete FSCA Report → Verify and Submit

Arrive on the OSCAR landing page.

The menu bar may appear different depending on your roles.

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Click on *Create FSCA Report* in the sidebar.

* If this link is not present, please contact your Company OSCAR Administrator to assign the FSCA module role to your user account.

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Login → **Create Final FSCA Report** → Complete FSCA Report → Verify and Submit

Select *Existing Case* and enter the FSCA reference number for the case you wish to submit the Final Report and click *OK*.

Create an FSCA Report

* Create FSCA Report   ○ New Case ⦿ Existing Case

* FSCA Ref No   2020-FSCA-000000

[OK] [Cancel]

Guide For Final FSCA Report Submission

Login → **Create Final FSCA Report** → **Complete FSCA Report** → **Verify and Submit**

You may verify in the case information that this is the case for which you wish to submit the Final Report.

Then, click on the *Add* ➕ button at the top right hand corner.

Case Information

Special Characters e.g. # ( ) , ; > < ' are not allowed in all text fields.

Reports

Select	Sub Report RefNo.	Type of Report	Device Name	Report Status	Date/Time of submission
☐	2020-FSCA-000001-NR01	Notification Report	Test Device	Submitted	06/04/2020 10:00:00 AM

Case Information

* Type Of Field Safety Corrective Action (FSCA): ⦿ Product Recall ◯ Other Corrective Actions

* Type of Report: ⦿ Notification Report ◯ Preliminary Report ◯ Follow Up Report ◯ Final Report

* FSCA Ref No.: 2020-FSCA-000001

* Sub Report Ref No.: 2020-FSCA-000001-NR01

* Date of Submission: 06/04/2020 10:00:00 AM

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Login → **Create Final FSCA Report** → Complete FSCA Report → Verify and Submit

Select *Final* Report in the drop-down list and click *OK.*

Create Report

Type of Submission:

- Notification Report
- Preliminary Report
- FollowUp Report
- **Final Report**

OK

Type of Submission

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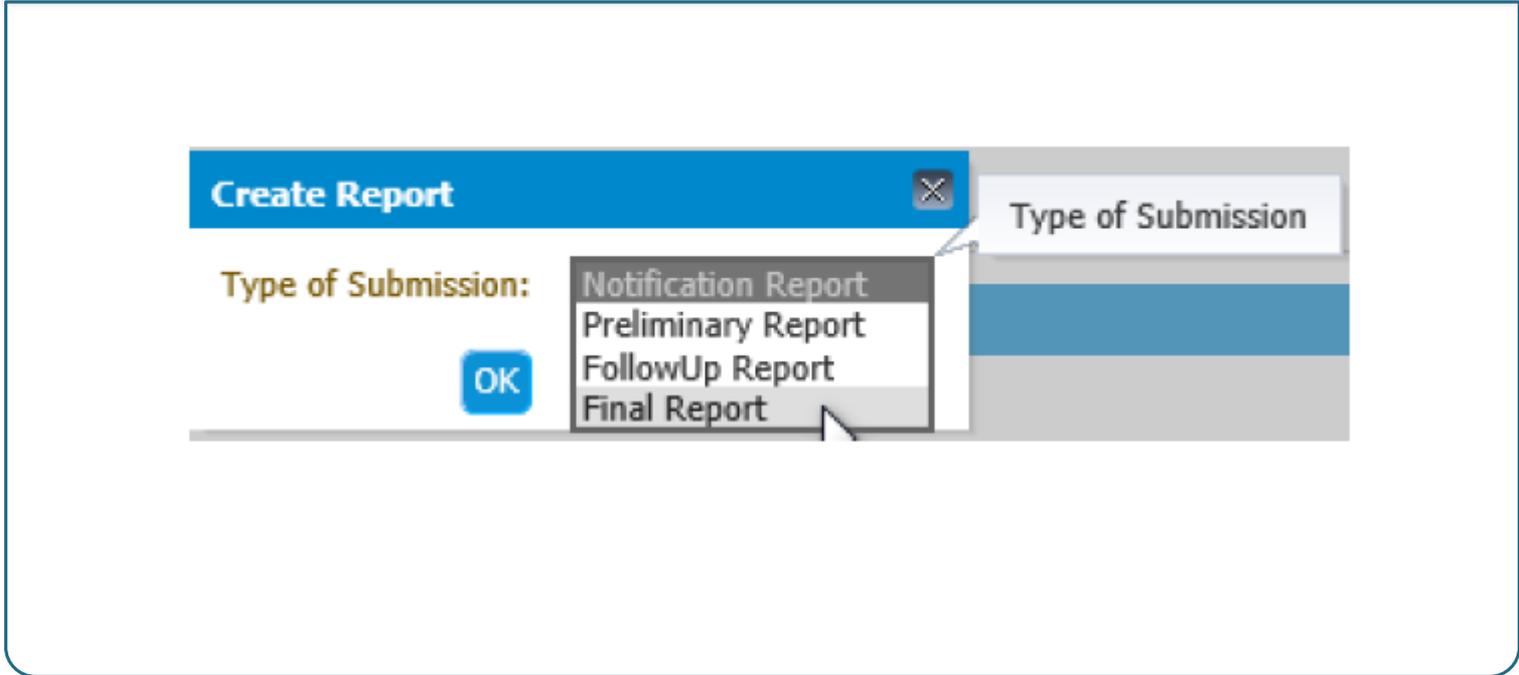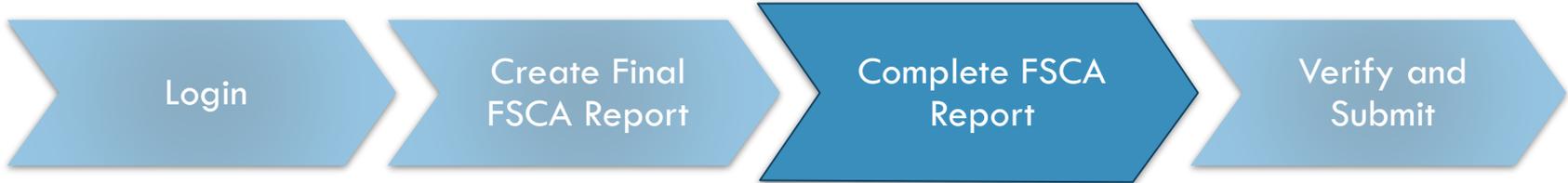
Read the instructions carefully and click on *Close* when you are done.

Instructions

FIELD SAFETY CORRECTIVE ACTION

FOLLOW-UP / FINAL REPORT (MDRR2 Form)

1. This form may take you 15 minutes to fill in. You will need to prepare certain information in order to complete the form.
2. This form serves as the prescribed form for reporting under Regulations 45(1)(b) and 47(1)(b) of the Health Products (Medical Devices) Regulations 2010.
3. If the space provided in the form is insufficient, please provide the information as an attachment.
4. This report is to be submitted no later than 21 days after the commencement of the field safety corrective action.

Close

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Login → Create Final FSCA Report → **Complete FSCA Report** → Verify and Submit
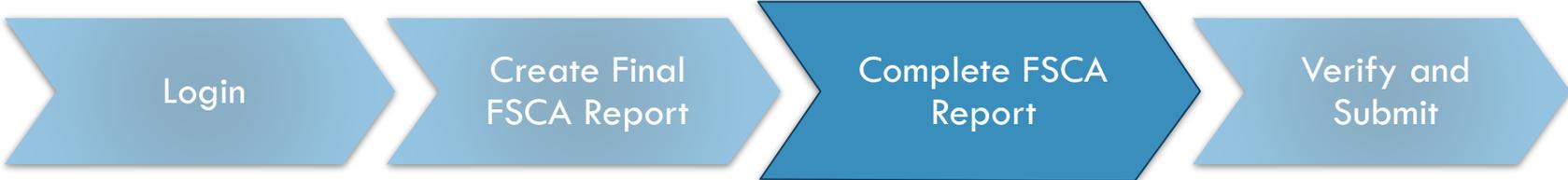
A new entry will be recorded in the Reports section and Report Status will show *Draft*.

▼ Reports				
Select	**Sub Report RefNo.**	**Type of Report**	**Device Name**	**Report Status**
☐	2020-FSCA-000001-NR01	Notification Report	Test Device	Submitted
☐	2020-FSCA-000001-FR01	Final Report	Test Device	Draft

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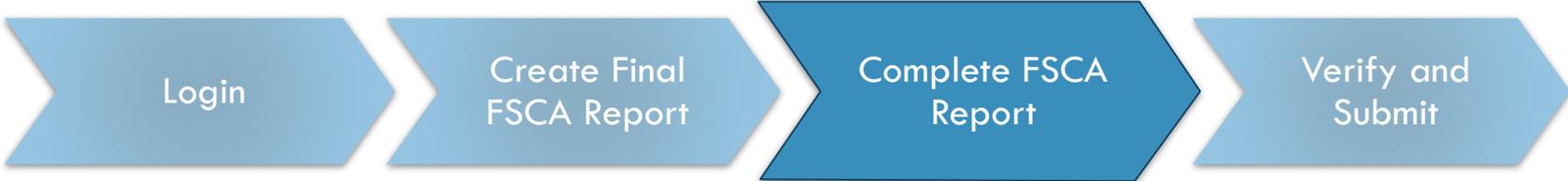
In the FSCA Information section, you are required to clarify if the FSCA was completed. If yes, please provide the date of completion.

If the FSCA has not been completed, you may wish to submit a Follow-up report instead.

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Login → Create Final FSCA Report → **Complete FSCA Report** → Verify and Submit
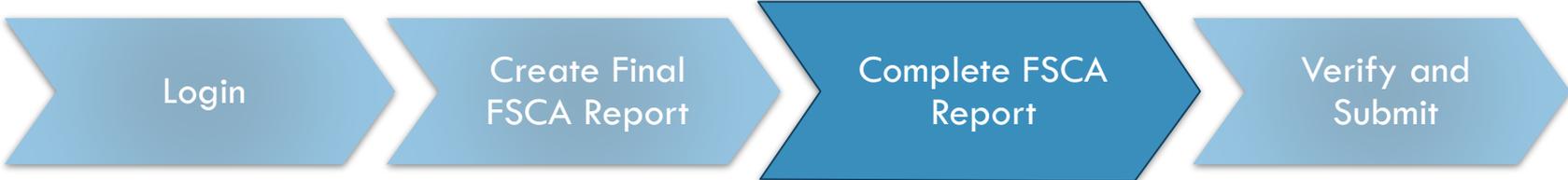
Provide the actions taken on the affected devices and upload any documentary proof in the *Other Attachments* field.

☑ Action taken on affected products

I confirm that the action has been completed on [＿＿＿＿＿] 📅 dd/mm/yyyy

I will be

☐ returning the affected stocks to the product owner as approved by the Authority*.

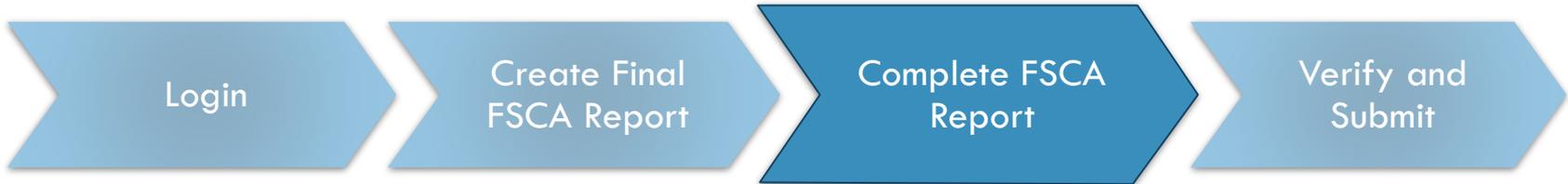☐ destroying the affected stocks as approved by the Authority* at (location and date) [＿＿＿＿＿]

☐ Other action(s) as approved by the Authority* , please specify [＿＿＿＿＿] (* To provide documentary proof of action(s) taken)
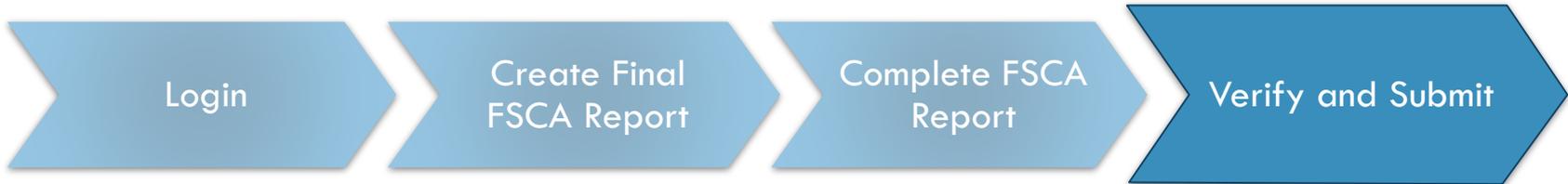
☑ Other Information

Other Information: [＿＿＿＿＿]

Other Attachments: [Please Select ▼] [＿＿＿＿＿] [Browse...]

Guide For Final FSCA Report Submission

| Login | Create Final FSCA Report | Complete FSCA Report | Verify and Submit |

Complete the declaration section and click on the Submit button at the top right hand corner of the page after all information has been completed.

Save | Submit | Delete | Cancel

☑ **Declaration**

☑ I attest that the information submitted is true and accurate, and that I am authorized to submit this form on behalf of the company.

Date of this notification: 31/03/2020

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| Login | Create Final FSCA Report | Complete FSCA Report | Verify and Submit |

Verify the report information and click on *Yes* to submit the report.
You will then be informed if the report has been submitted successfully.

Confirmation Message

Are you sure you want to submit the task?

Yes   No

END

Updated as of July 2021