

Guide for Final FSCA Report Submission



OSCAR

Online Safety,
Compliance Application
and Registration
System

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



Click on the CorpPass logo.

Login to OSCAR?

————— LOG IN WITH —————



or



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Log in with UEN/Entity ID, CorpPass ID and Password

Singapore Corporate Access
CorpPass
BETA

Singapore Government
Integrity · Service · Excellence

Contact Us | Feedback | Sitemap | FAQ

CorpPass is now the ONLY login method for corporate transactions with the Government
Your entity can now transact with more than 140 government digital services. Register for CorpPass now to prevent any disruption to your business transactions!

Log in with CorpPass

UEN/ENTITY ID

CORPPASS ID

Password

Remember Entity ID

Forgot [Entity / CorpPass ID](#) or [Password](#)

Cancel Login

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Complete 2FA verification.

The screenshot shows the CorpPass interface. At the top left is the CorpPass logo with 'Singapore Corporate Access' above it. At the top right is the Singapore Government logo with the tagline 'Integrity · Service · Excellence'. Below the logo is a navigation menu with 'Contact Us | Feedback | Sitemap | FAQ'. A 'Log Out' button is visible in the top right corner. A large warning message is displayed in the center: 'You have not completed your 2FA setup. 2FA is required to access e-Service.' To the left of the message is a blue triangle with a white exclamation mark. Below the message is a small image of a smartphone displaying a OneKey Token. The text of the message reads: '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.' At the bottom of the message, it states: '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.' A blue 'Continue' button is located at the bottom center of the warning area.

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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.*

The screenshot shows the HSA logo at the top. Below it is a sidebar menu with the following structure:

- Tasks Search and Enquiry
- Applications (expanded)
- View (dropdown)
- Investigation FSCA (expanded)
- Create FSCA Report** (circled in red)

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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

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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.

Select	Sub Report RefNo.	Type of Report	Device Name	Report Status	Date/Time of submission
<input type="checkbox"/>	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.:

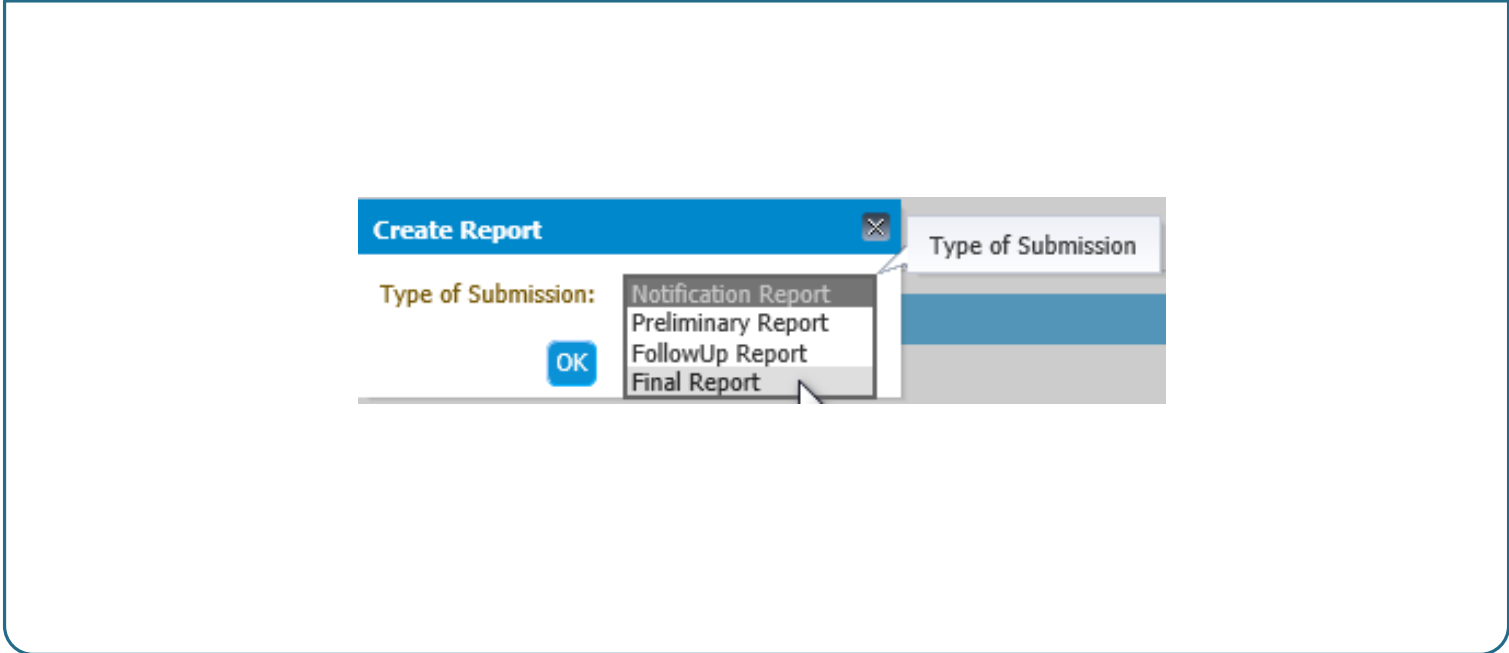
* Sub Report Ref No.:

* Date of Submission: 

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



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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](#)

Guide For Final FSCA Report Submission



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
<input type="checkbox"/>	2020-FSCA-000001-NR01	Notification Report	Test Device	Submitted
<input type="checkbox"/>	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.

FSCA Information

* FSCA completed: Yes No

Effectiveness checks on operational conduct of FSCA:

Final risk evaluation (if different from the initial risk evaluation):

Summary of Product Owner's Corrective and Preventive action and effectiveness checks

Calendar: April 2020

SUN	MON	TUE	WED	THU	FRI	SAT
29	30	31	1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	1	2

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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:

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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

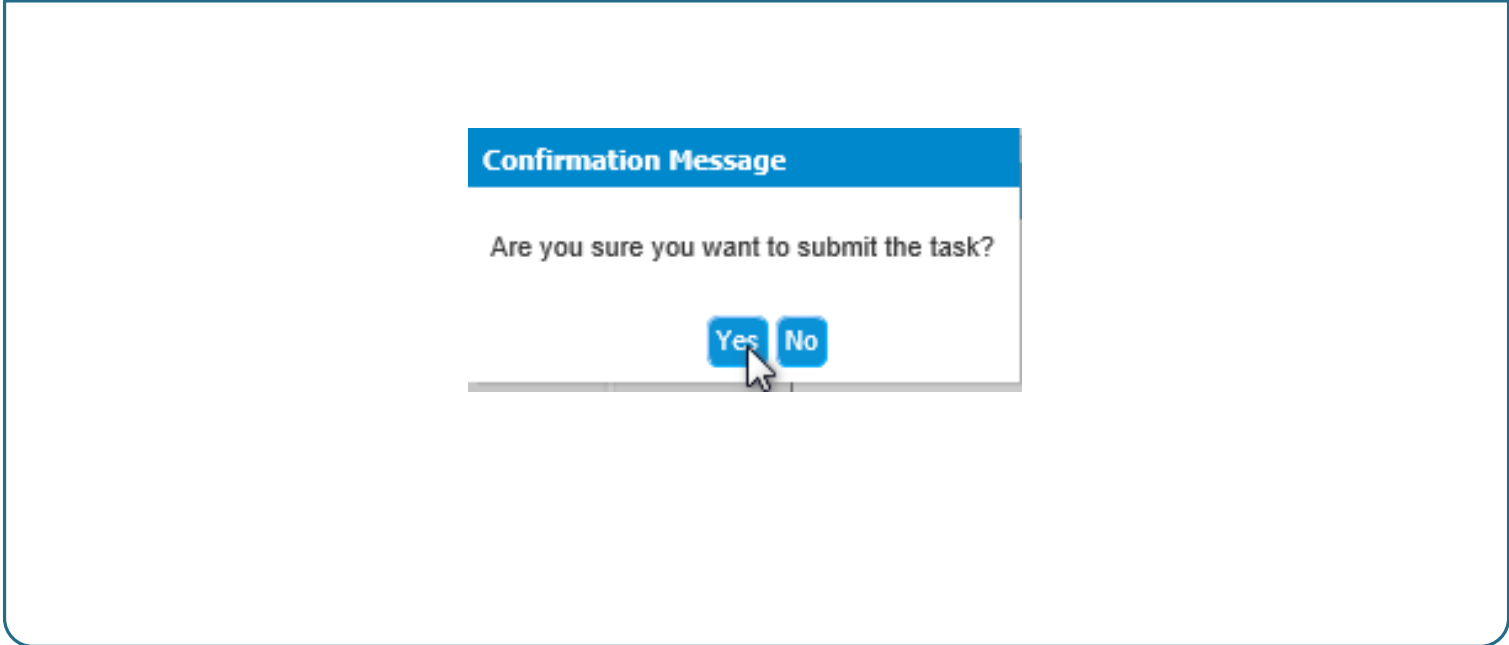
I attest that the information submitted is true and accurate, and that I am authorized to submit this form on behalf of the company.

Date of this notification:

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



END



Updated as of Apr 2020