Guide for New FSCA Report Submission

HSA
Health Sciences Authority

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.

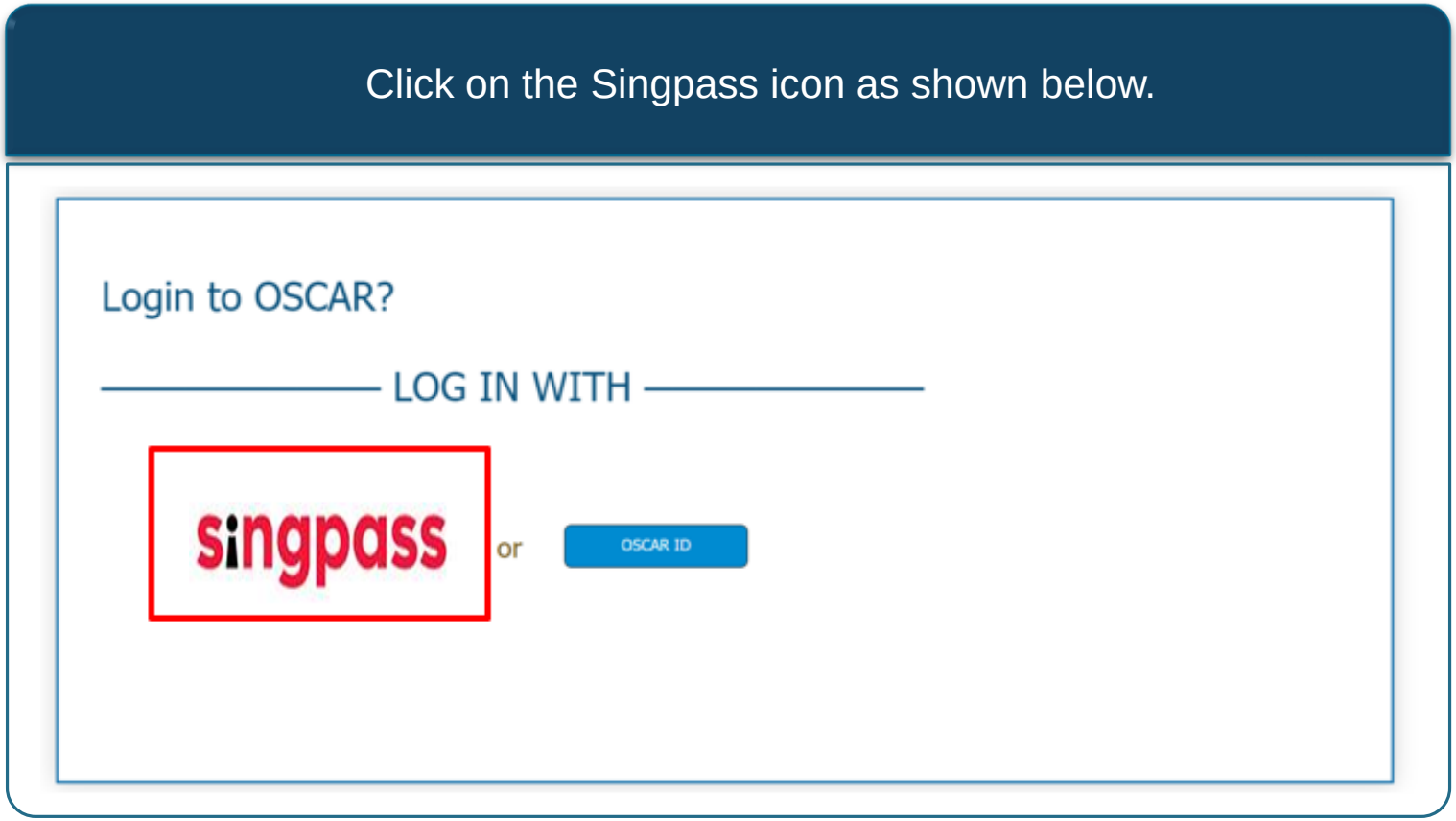
- If you do not have an OSCAR account, please contact your company's OSCAR Administrator(s) for creation of your OSCAR user account.

- Due to the initiative from Singpass Corppass team, there is a change in the Corppass login process. While Singpass is used for logins, Corppass will remain as the authorisation system for access.

Guide For New FSCA Report Submission

Login → Create New FSCA Report → Complete FSCA Report → Verify and Submit

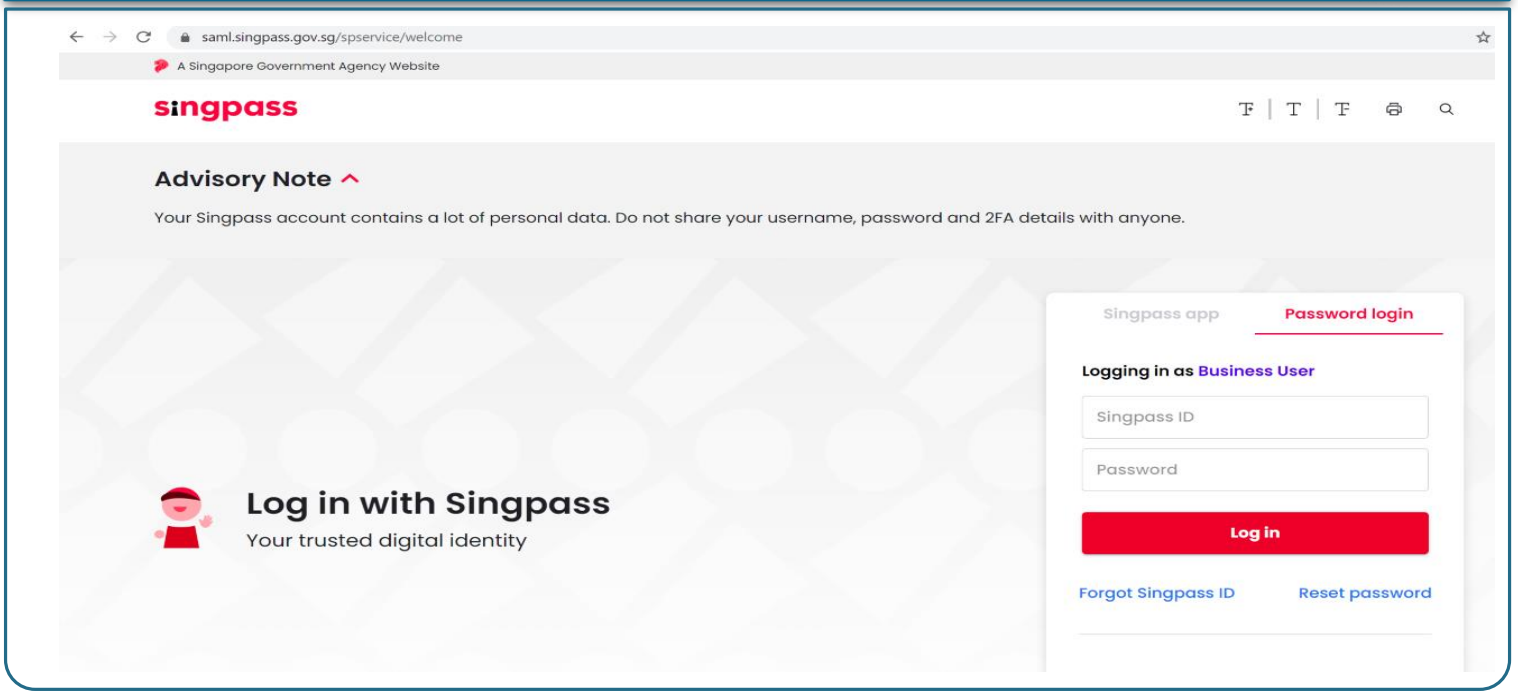
Click on the Singpass icon as shown below.



Guide For New FSCA Report Submission

Login → Create New FSCA Report → Complete FSCA Report → Verify and Submit

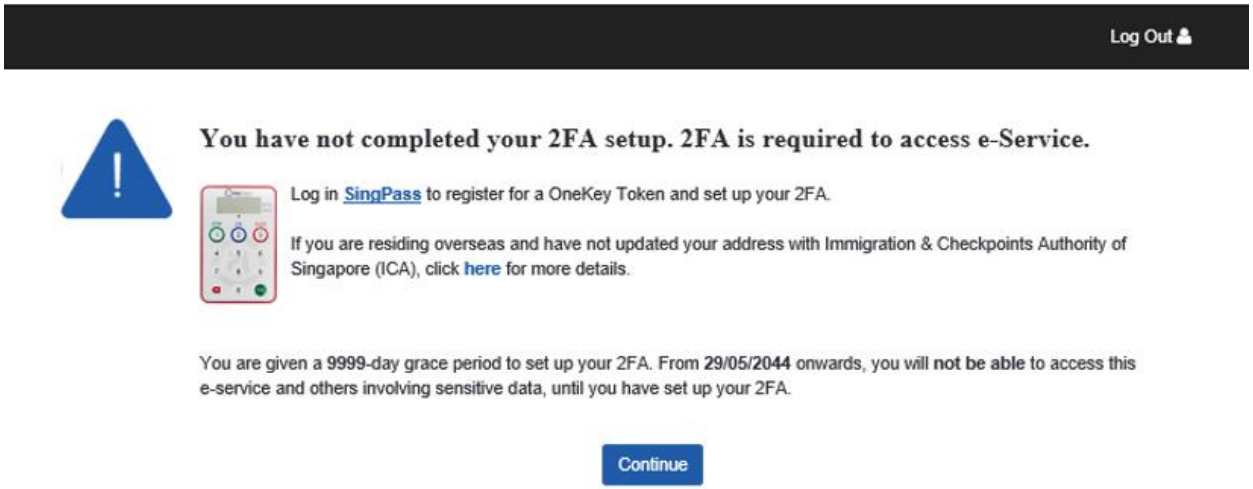
Enter the details and click on log in



Guide For New FSCA Report Submission

Login → Create New FSCA Report → Complete FSCA Report → Verify and Submit

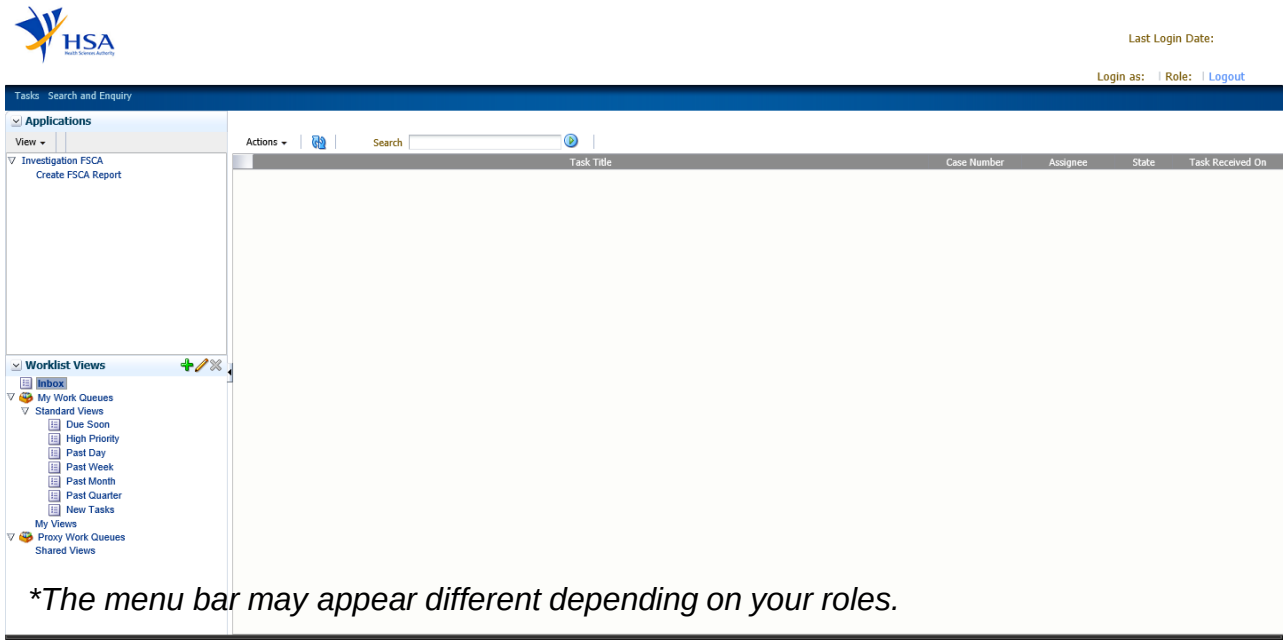
Complete 2FA verification.



Guide For New FSCA Report Submission

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

Arrive on the OSCAR landing page.



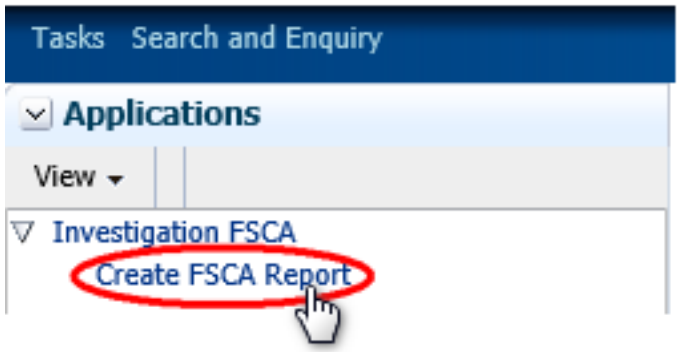
**The menu bar may appear different depending on your roles.*

Guide For New FSCA Report Submission

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

Click on *Create FSCA Report* in the sidebar.

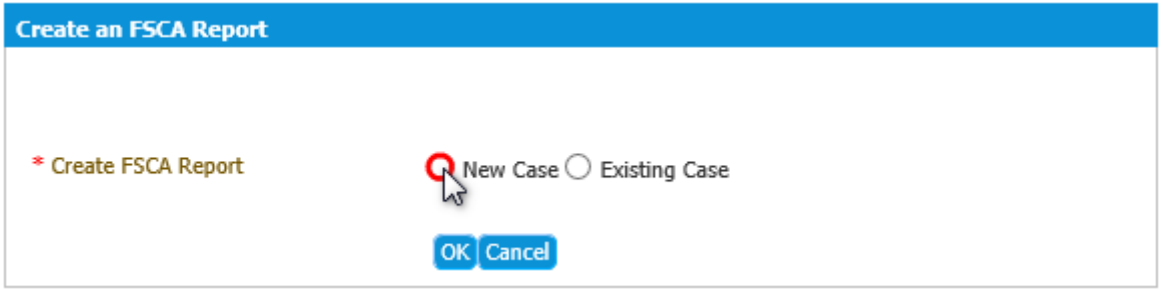
** If this link is not present, please contact your Company OSCAR Administrator to assign the FSCA module role to your user account.*



Guide For New FSCA Report Submission

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

Select *New Case* and click OK.

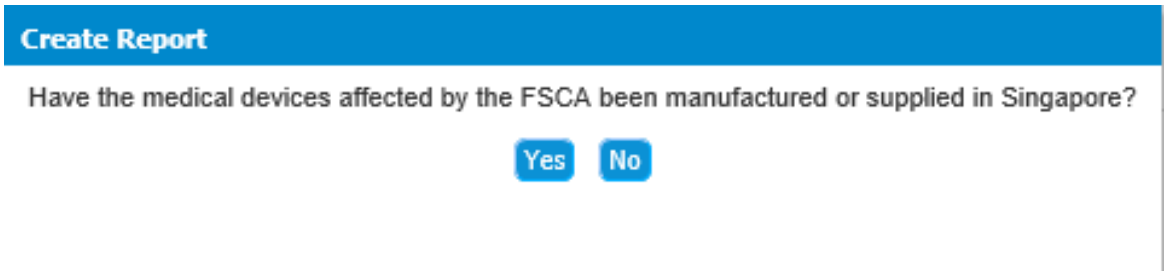


Guide For New FSCA Report Submission

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

Declare if the medical devices affected by the FSCA have been manufactured or supplied in Singapore.

**Refer to GN-10 Guidance on Medical Device Field Safety Corrective Action to determine if the FSCA is reportable.*



Guide For New FSCA Report Submission

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

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

Instructions

FIELD SAFETY CORRECTIVE ACTION

NOTIFICATION / PRELIMINARY REPORT (MDRR1 Form)

1. This form may take you 30 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 44, 45(1)(a), 46 and 47(1)(a) of the Health Products (Medical Devices) Regulations 2010.
3. For registered medical devices that are correction-in-progress medical devices, this form may additionally serve as the prescribed form in accordance to Regulation 49 of the Health Products (Medical Devices) Regulations 2010 for notification of the changes related to the correction.
4. For corrected medical devices, prior to new supply, verify whether a Change Notification (CN) submission through the Medical Device Information & Communication System (MEDICS) is required. If a MEDICS CN submission and approval is necessary, new supply shall not proceed unless prior approval from HSA has been received.
5. If the space provided in the form is insufficient, please provide the information as an attachment.
6. Please be advised that any Field Safety Notices (FSN) issued by you may be published as-is on the HSA website. You are required to take full responsibility for the information contained in the FSN and must indemnify HSA for all losses, claims, demands, liabilities, causes of actions, expenses of any kind arising from HSA's publication of the FSN.

Close

Instructions

MEDICAL DEVICE POST-MARKET

INFORMATION REPORT (MDRR3 Form)

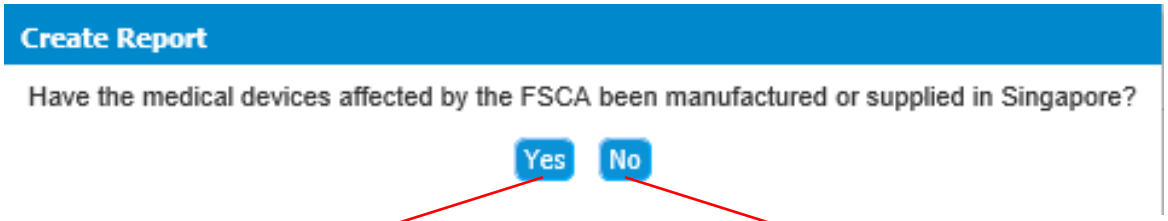
1. This form may take you 30 minutes to fill in. You will need to prepare certain information to fill in the form.
2. This form serves as the prescribed form for reporting of information related to product defects under the Health Products (Medical Devices) Regulations 2010. This form serves concurrently as a general post-market information report form.
3. If the space provided in the form is insufficient, please provide the information as an attachment.
4. (Applicable to FSCA reporting only) Please be advised that any Field Safety Notices (FSN) issued by you may be published as-is on the HSA website. You are required to take full responsibility for the information contained in the FSN and must indemnify HSA for all losses, claims, demands, liabilities, caused of actions, expenses of any kind arising from HSA's publication of the FSN.

Close

Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR1/MDRR3)** → Verify and Submit

Depending on your declaration, the relevant FSCA form will be presented.
All fields marked with a red asterisk * is mandatory.



For MDRR1 instructions, click here.

For MDRR3 instructions, click here.

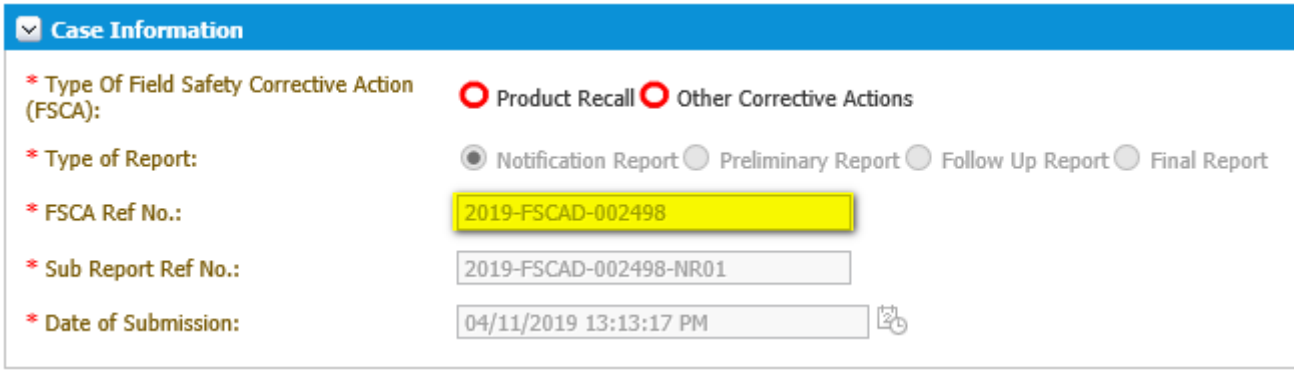
Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR1)** → Verify and Submit

In the Case information section, indicate the type of FSCA.

**Note that the Ref No. 20XX-FSCAD-XXXXXX is the draft number for the report. The actual FSCA Reference Number will only be issued after the case has been submitted.*

Case Information



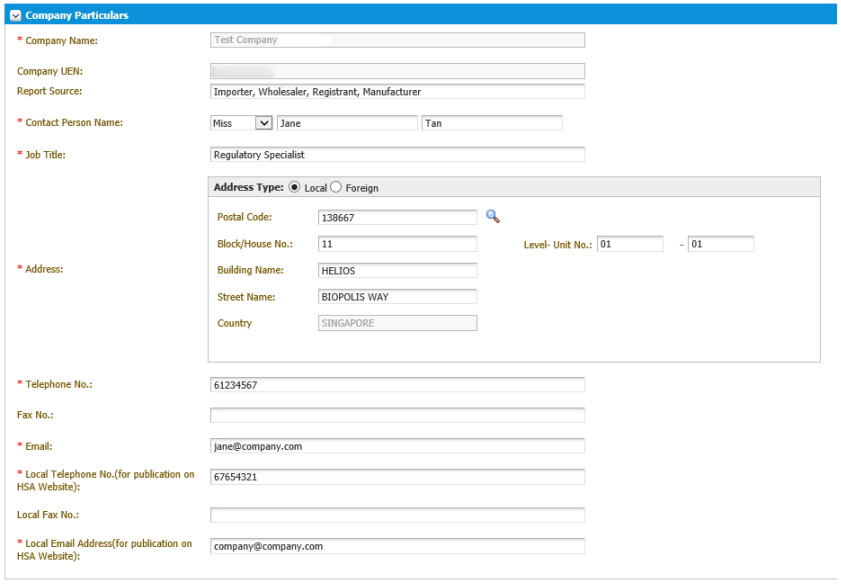
Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR1)** → Verify and Submit

For Report Source, please indicate if the reporting company is the Importer, Wholesaler, Registrant, and/or Manufacturer of the affected devices.

For local addresses, you may enter the postal code and click on 🔍 .

Company Particulars

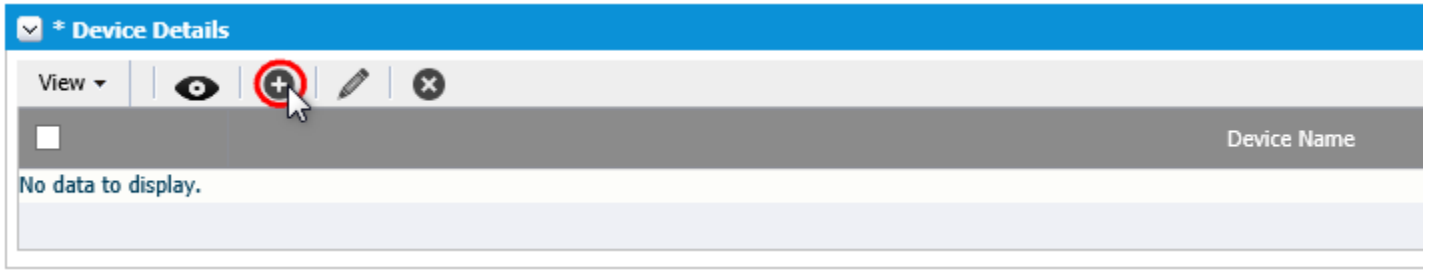


Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR1)** → Verify and Submit

To add details of the affected device, please click on the *Add* button.

Device Details

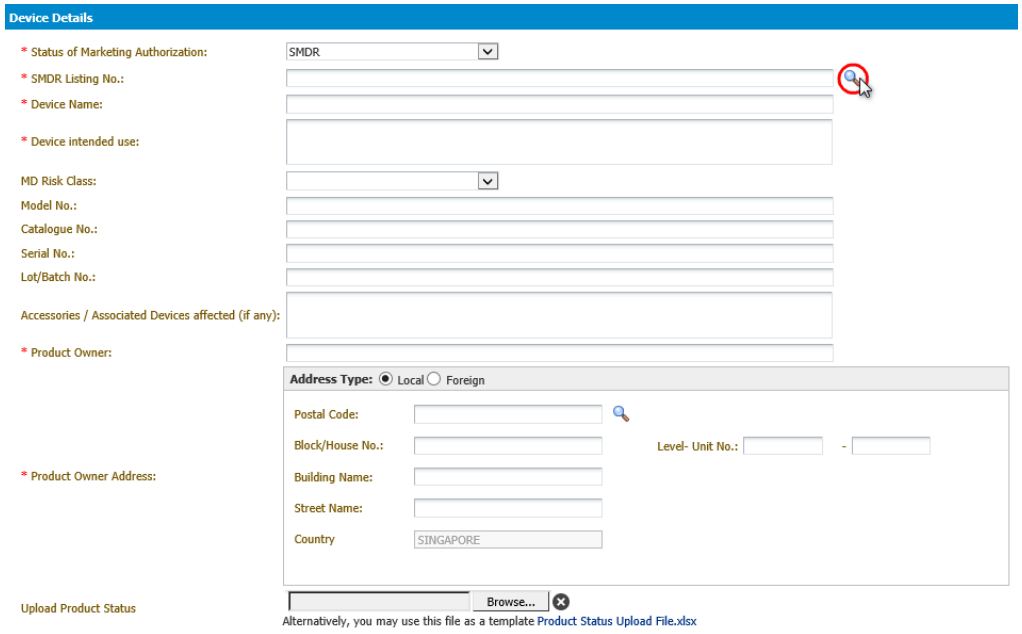


Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR1)** → Verify and Submit

If the affected device is registered on SMDR, you may click on 🔍 to display all registered listings and select your affected listing.

Device Details



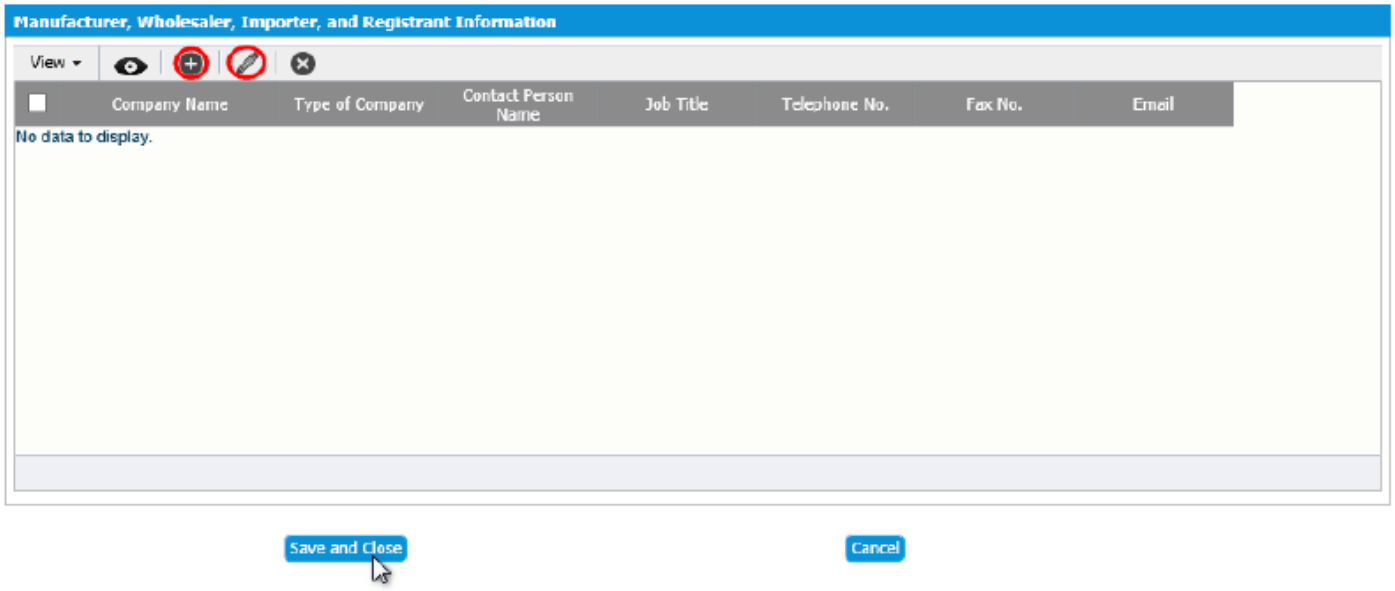
Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR1)** → Verify and Submit

Click on the *Add* button or *Edit* button to complete the Manufacturer, Wholesaler, Importer, and Registrant Information.

Click on Save and Close after the information is complete.

Device Details

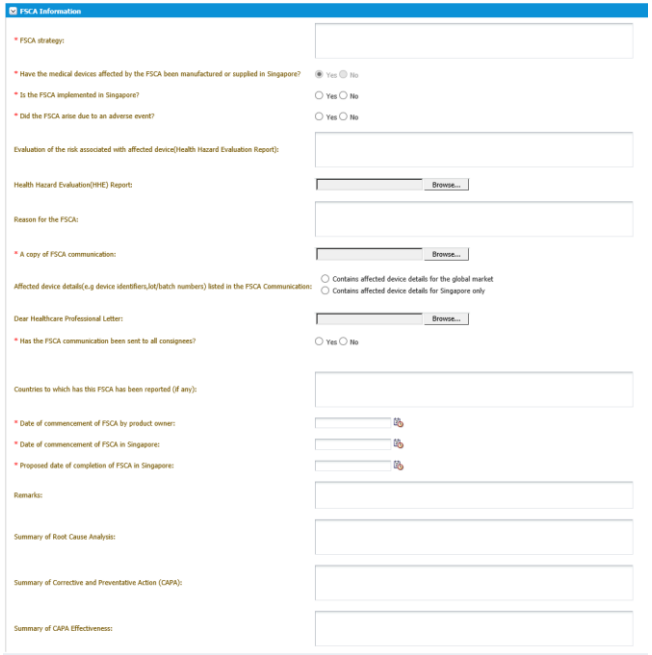


Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR1)** → Verify and Submit

Complete the FSCA Information section and ensure that all fields marked with an asterisk * is completed.
You may hover the mouse pointer over the field titles for details on the required information.

FSCA Information



Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR1)** → Verify and Submit

If applicable, provide details on the list of changes that will be implemented by the software update and complete the table.

Change Notification Details (If applicable)

Change Notification Details(if applicable)

Type of change with reference to GN-21 (e.g software change, design change, labelling change):

For software-related changes have any features not related to this FSCA been incorporated?(If Yes, please provide further details in the Software Details table below): ○ Yes ○ No

Software Details:

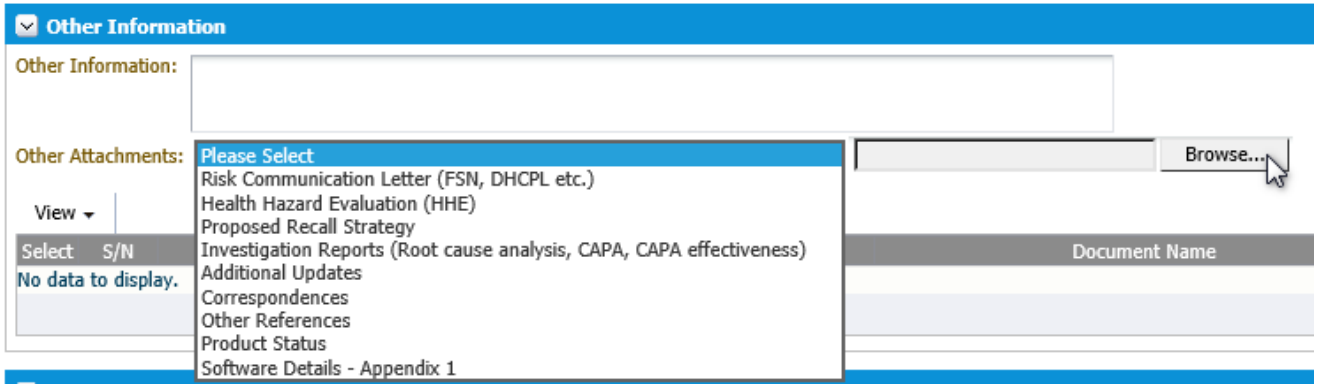
Software Details	Current Approved	Proposed
Name of Software		
Version Number		
Intended use of the software		
Description of the differences between current and proposed software.		

Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR1)** → Verify and Submit

You may upload supporting documents and include any additional comments in the Other Information field.
Please note that the document to be uploaded must not be an empty document

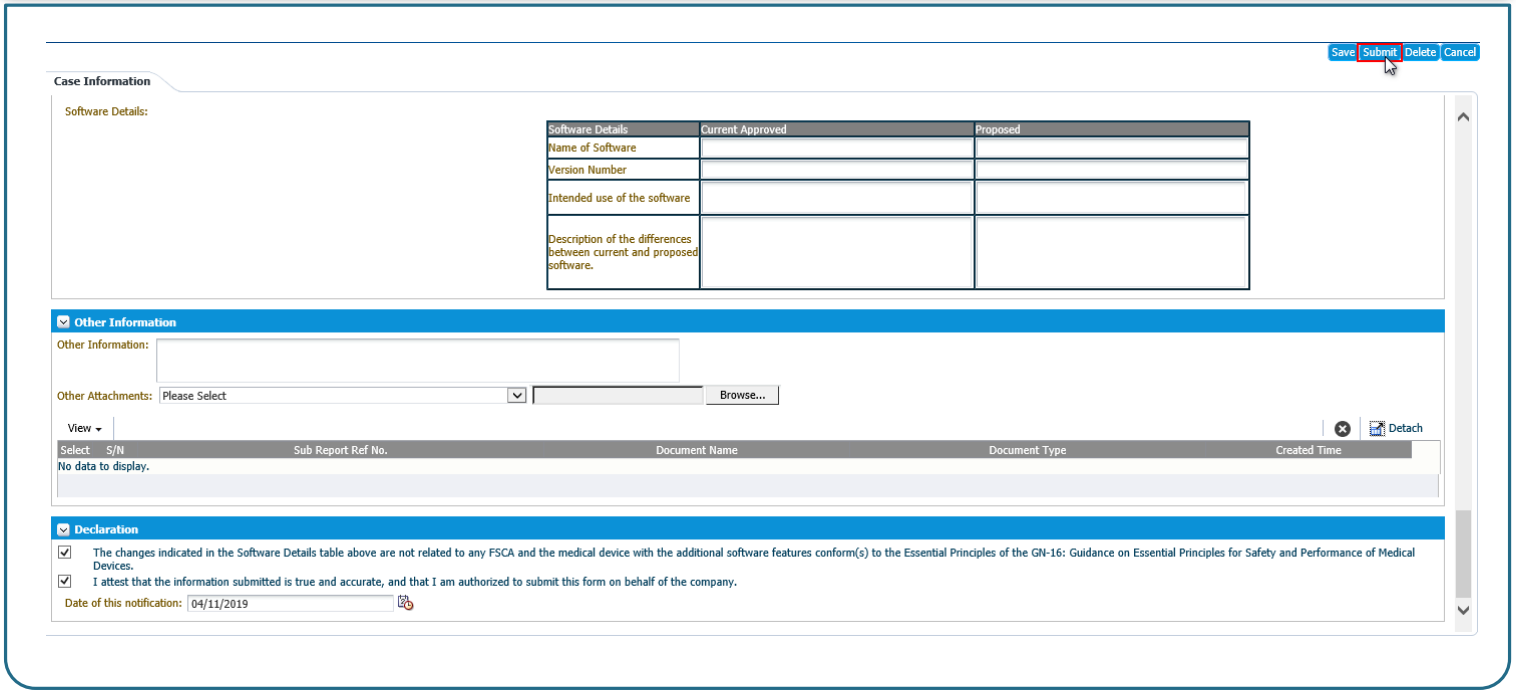
Other Information



Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR1)** → Verify and Submit

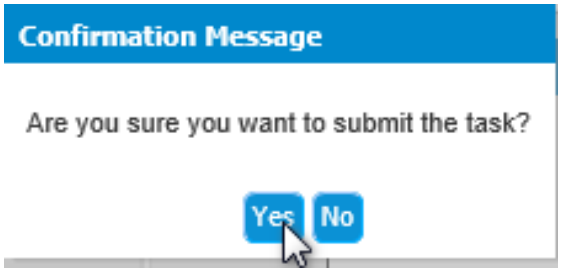
Complete the declaration section and click on the Submit button at the top right hand corner of the page after all information has been completed.



Guide For New FSCA Report Submission

Login → Create New FSCA Report → Complete FSCA Report → Verify and Submit

Verify the report information and click on Yes to submit the report.



Guide For New FSCA Report Submission

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

Please note down the FSCA Reference Number issued after report submission.
For communications with HSA regarding the FSCA reported, kindly quote this FSCA Reference Number.

MDRR1 submission is completed.

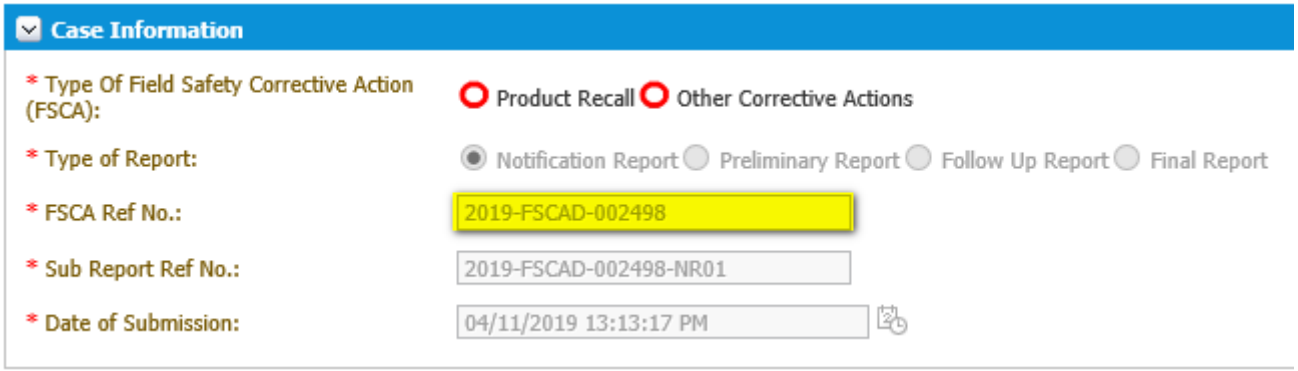
Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR3)** → Verify and Submit

In the Case information section, indicate the type of FSCA.

**Note that the Ref No. 20XX-FSCAD-XXXXXX is the draft number for the report. The actual FSCA Reference Number will only be issued after the case has been submitted.*

Case Information



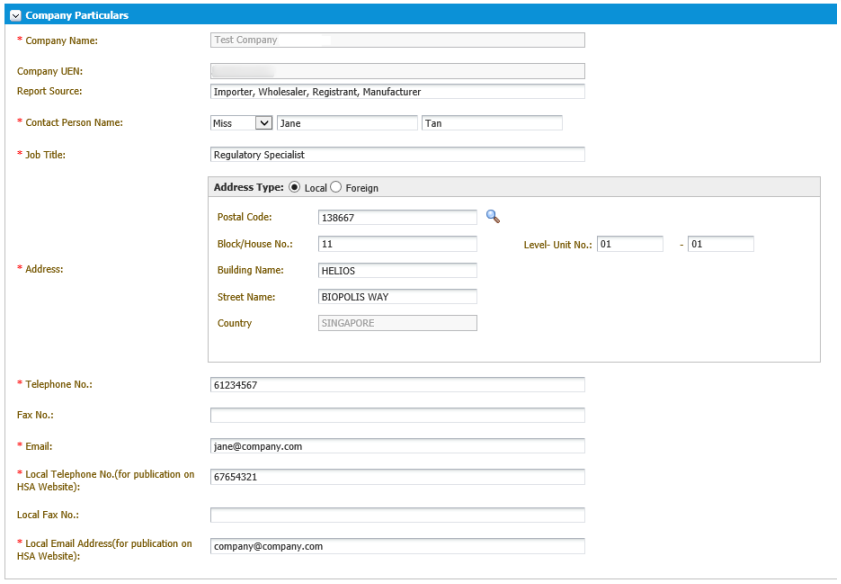
Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR3)** → Verify and Submit

For Report Source, please indicate if the reporting company is the Importer, Wholesaler, Registrant, and/or Manufacturer of the affected devices.

For local addresses, you may enter the postal code and click on 🔍 .

Company Particulars

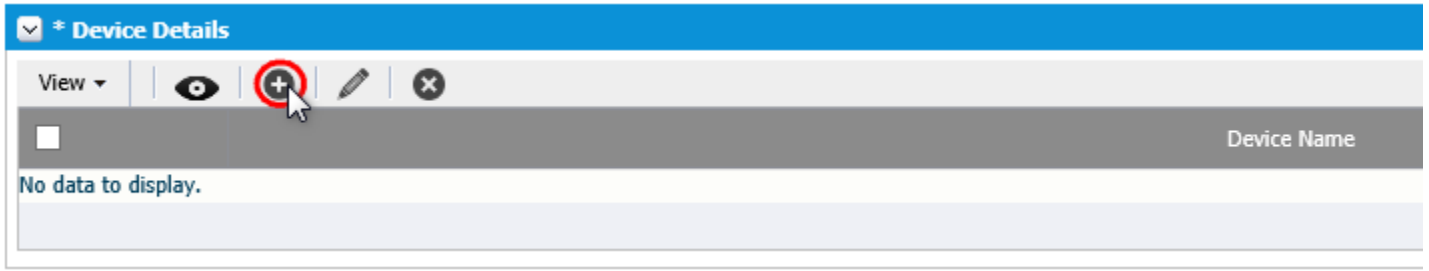


Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR3)** → Verify and Submit

To add details of the affected device, please click on the *Add* button.

Device Details

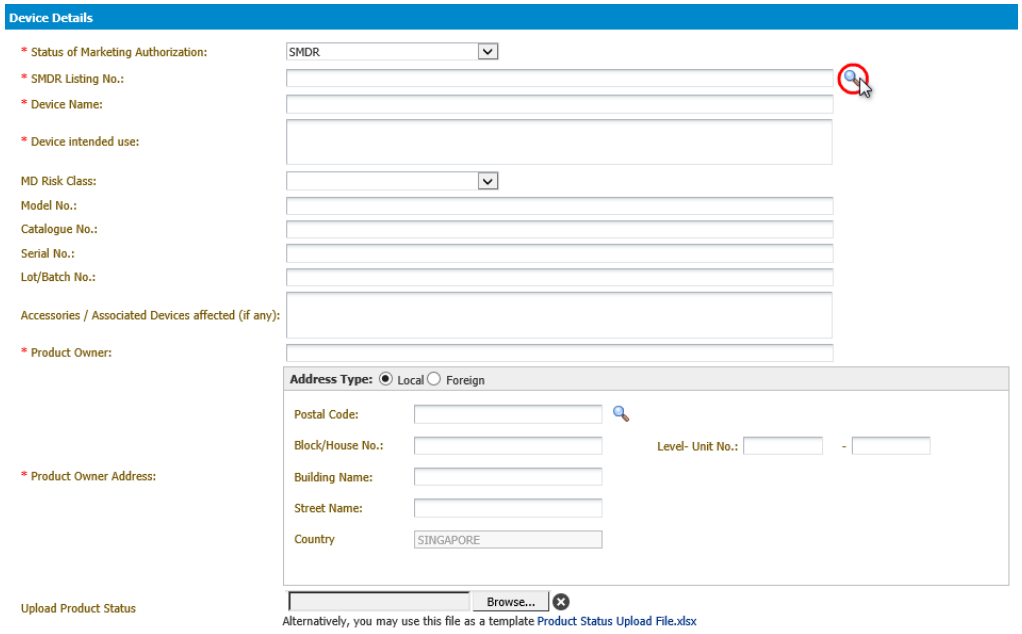


Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR3)** → Verify and Submit

If the affected device is registered on SMDR, you may click on 🔍 to display all registered listings and select your affected listing.

Device Details



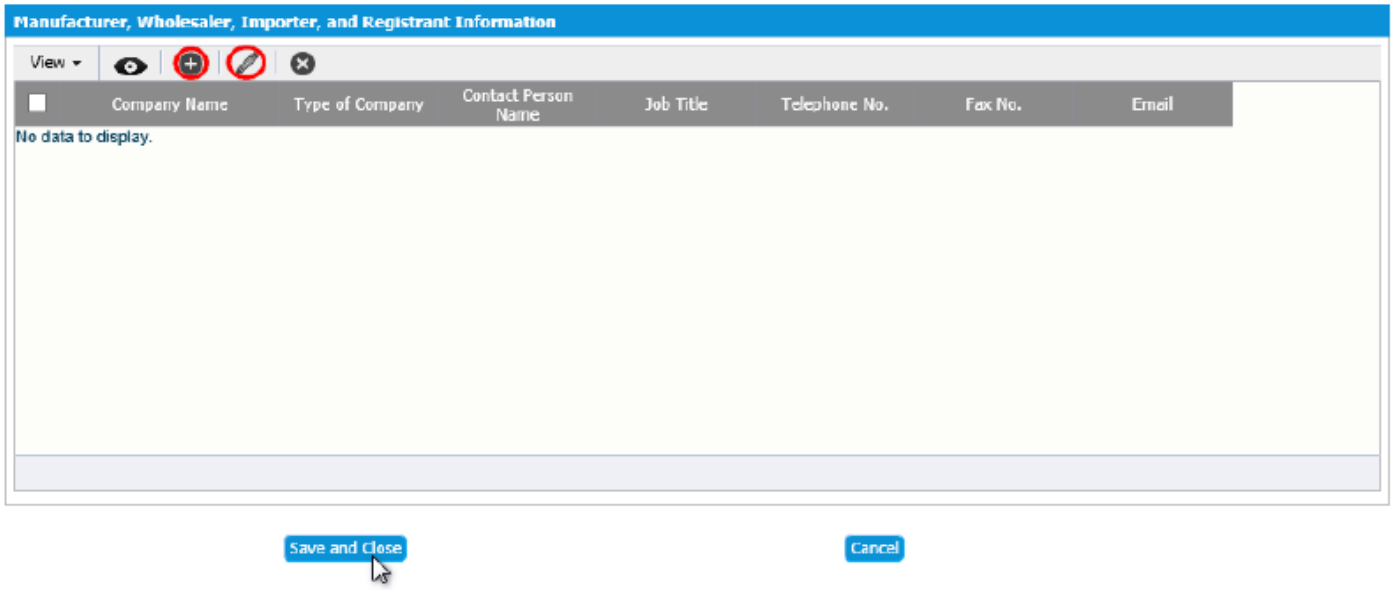
Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR3)** → Verify and Submit

Click on the *Add* button or *Edit* button to complete the Manufacturer, Wholesaler, Importer, and Registrant Information.

Click on Save and Close after the information is complete.

Device Details



Guide For New FSCA Report Submission

Login → Create New FSCA Report → Complete FSCA Report **(MDRR3)** → Verify and Submit

Select the type of post-market information to be submitted in this report.

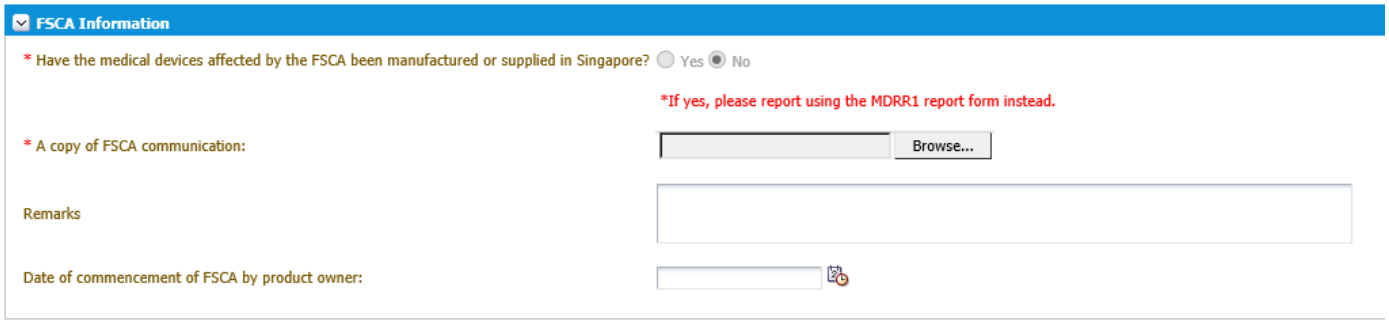
Medical Device Post-Market Information

Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR3)** → Verify and Submit

Provide a copy of the FSN and date of commencement of FSCA by the product owner.

FSCA Information



Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR3)** → Verify and Submit

If applicable, complete the product defect/complaint information section

Product Defect or Complaint Information

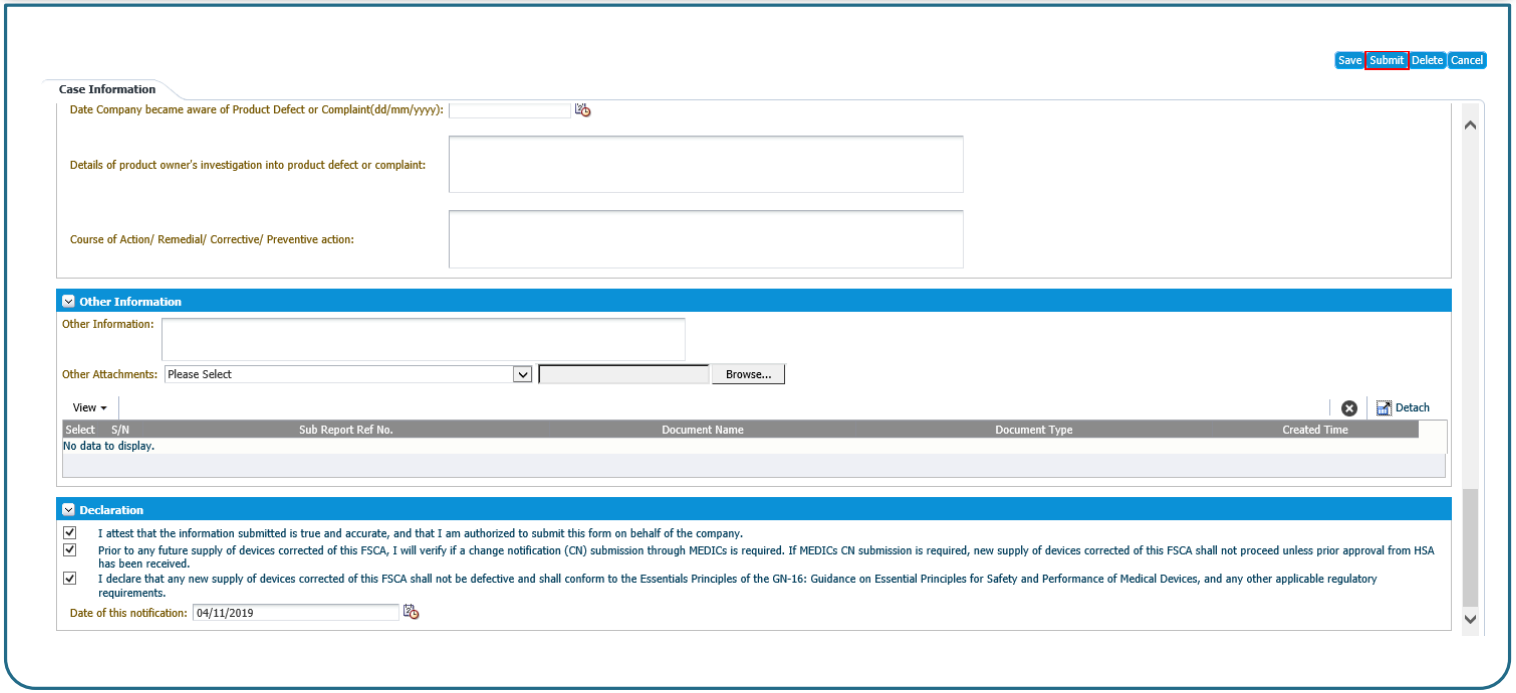
Medical Device Product Defect or Complaint Information (Where applicable)

Description of Product Defect or Complaint:	
Date Company became aware of Product Defect or Complaint(dd/mm/yyyy):	
Details of product owner's investigation into product defect or complaint:	
Course of Action/ Remedial/ Corrective/ Preventive action:	

Guide For New FSCA Report Submission

Login → Create New FSCA Report → **Complete FSCA Report (MDRR3)** → Verify and Submit

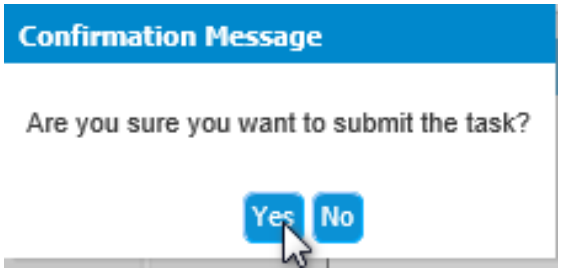
Complete the declaration section and click on the Submit button at the top right hand corner of the page after all information has been completed.



Guide For New FSCA Report Submission

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

Verify the report information and click on Yes to submit the report.

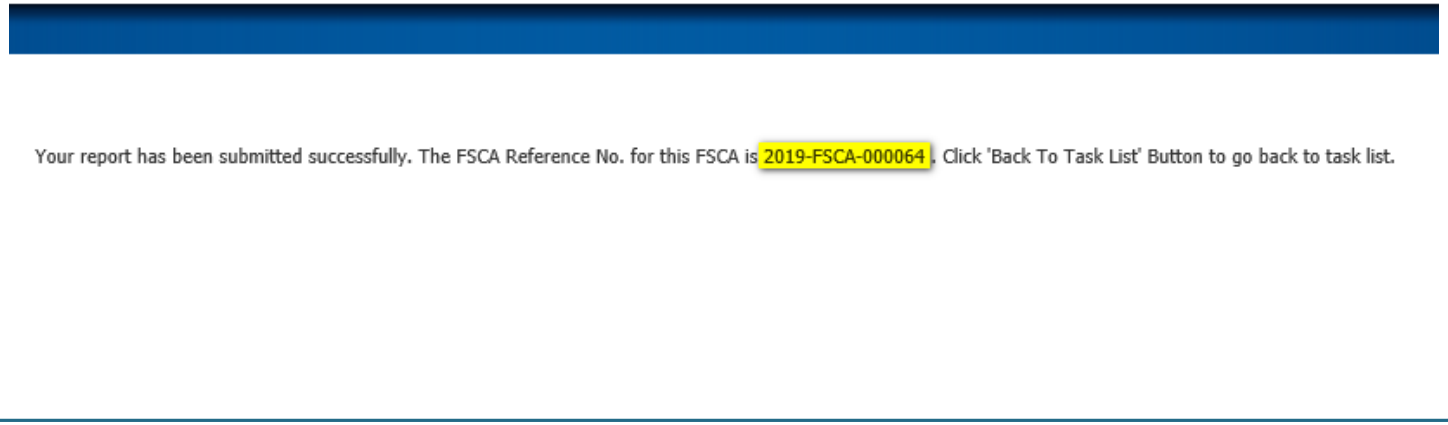


Guide For New FSCA Report Submission

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

Please note down the FSCA Reference Number issued after report submission.
For communications with HSA regarding the FSCA reported, kindly quote this FSCA Reference Number.

MDRR3 submission is completed.



END

Updated as of July 2021