

Guide for New FSCA Report Submission



OSCAR

Online Safety,
Compliance Application
and Registration
System

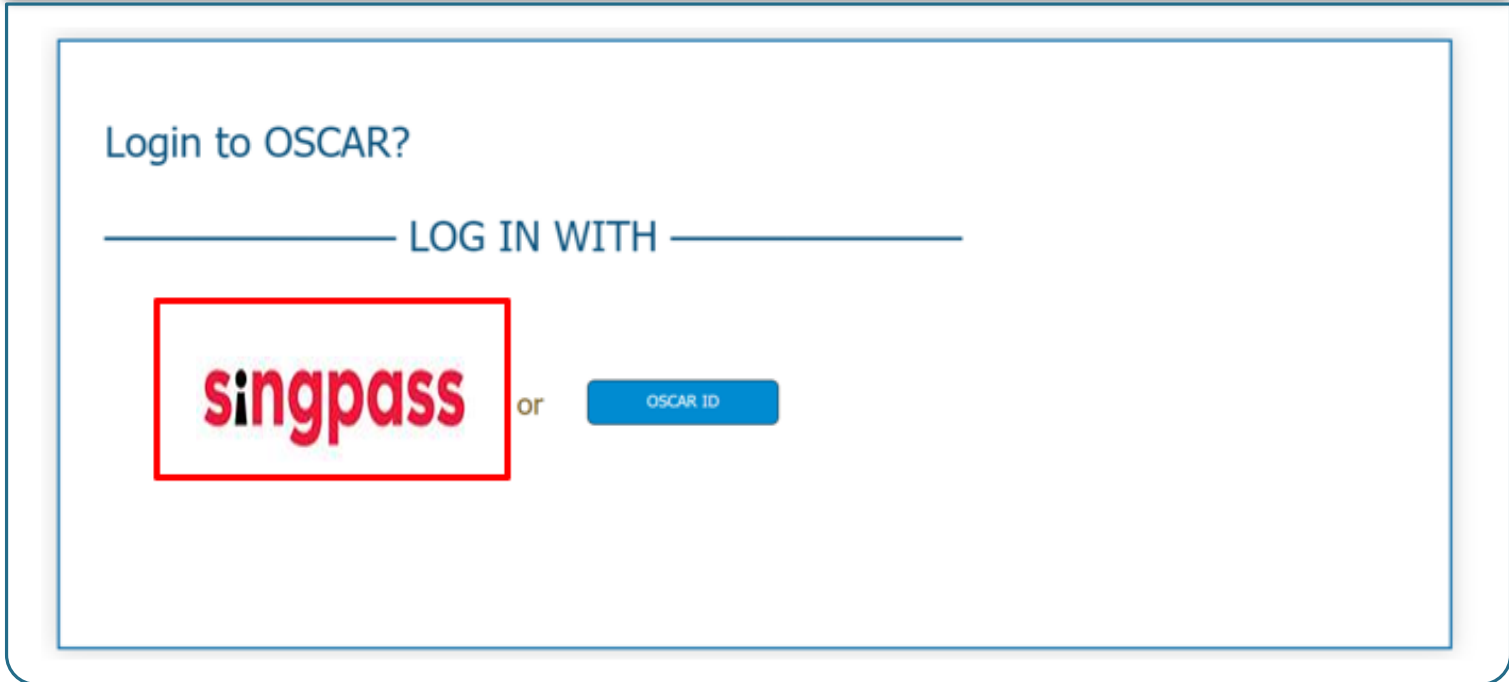
IMPORTANT NOTES

- ❑ 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.
- ❑ 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



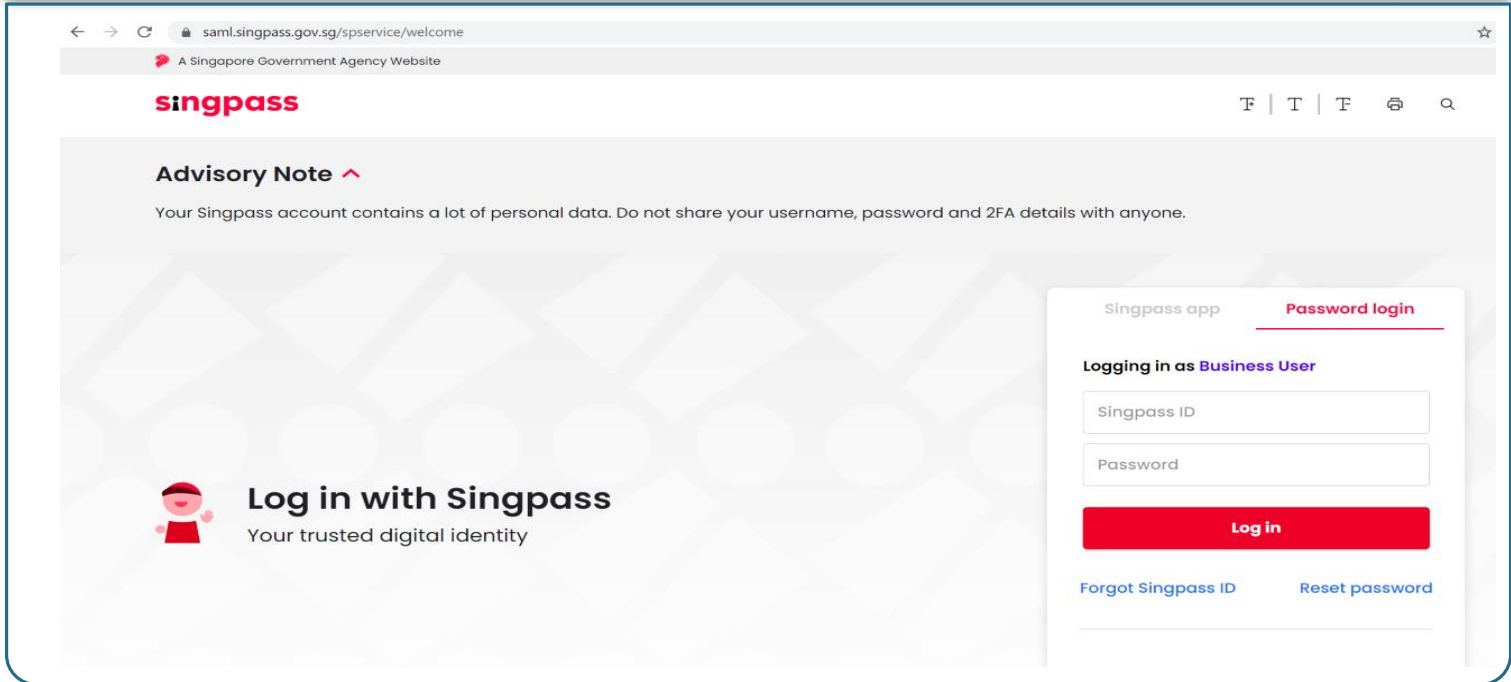
Click on the Singpass icon as shown below.



Guide For New FSCA Report Submission




Enter the details and click on log in



Guide For New FSCA Report Submission



Complete 2FA verification.

Log Out 



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



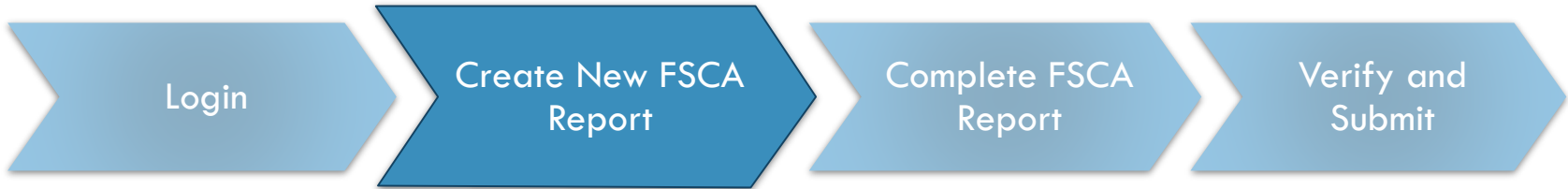
Log in [SingPass](#) to register for a OneKey Token and set up your 2FA.

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

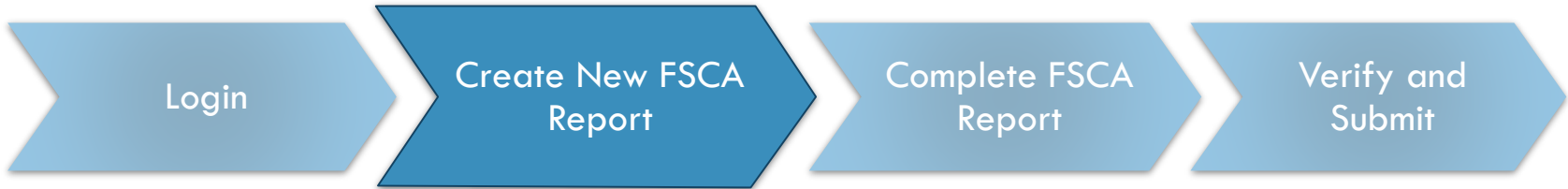
Guide For New FSCA Report Submission



Arrive on the OSCAR landing page.

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

Guide For New FSCA Report Submission

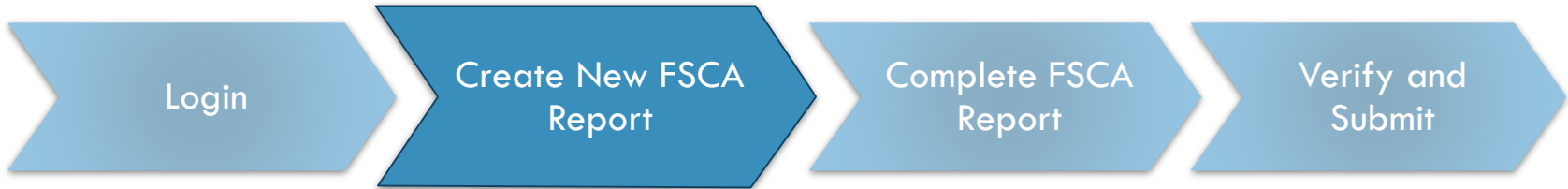


Click on *Create FSCA Report* in the sidebar.

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



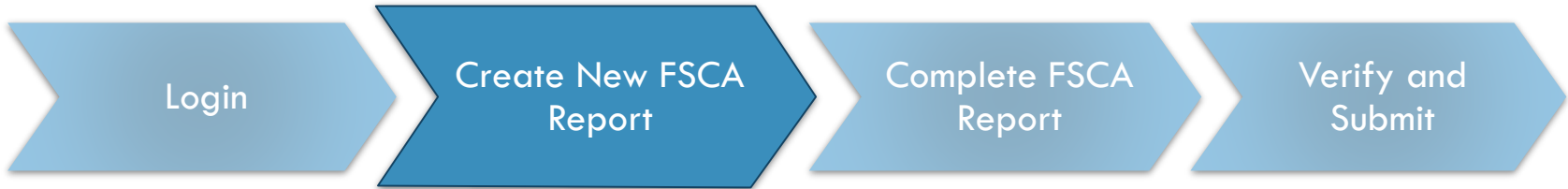
Guide For New FSCA Report Submission



Select *New Case* and click OK.

A screenshot of a software dialog box titled "Create an FSCA Report". The dialog has a blue header bar with the title. Below the header, there is a red asterisk followed by the text "Create FSCA Report". To the right of this text are two radio button options: "New Case" (which is selected, indicated by a red circle around the radio button) and "Existing Case". At the bottom of the dialog, there are two buttons: "OK" and "Cancel". A mouse cursor is pointing at the "New Case" radio button.

Guide For New FSCA Report Submission



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.*

Create Report

Have the medical devices affected by the FSCA been manufactured or supplied in Singapore?

Guide For New FSCA Report Submission



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



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

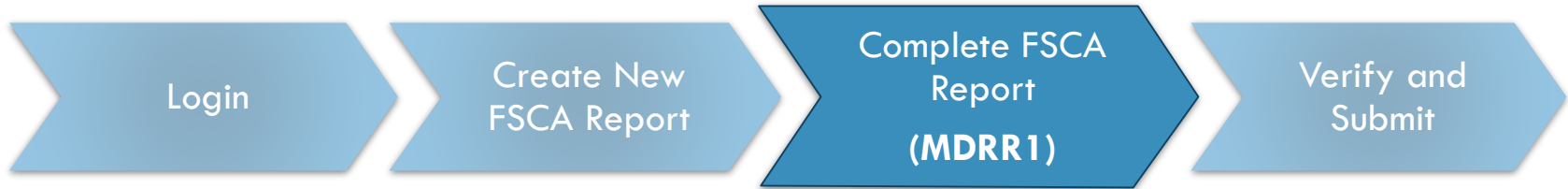
Create Report

Have the medical devices affected by the FSCA been manufactured or supplied in Singapore?

For MDRR1 instructions, click [here](#).

For MDRR3 instructions, click [here](#).

Guide For New FSCA Report Submission



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

Case Information

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

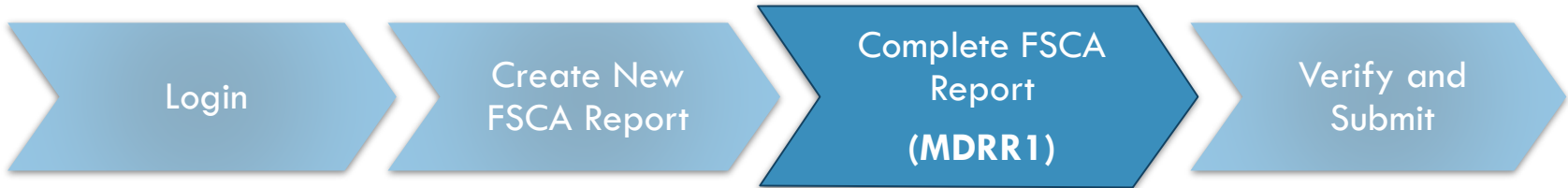
* Type of Report: Notification Report Preliminary Report Follow Up Report Final Report

* FSCA Ref No.:


* Sub Report Ref No.:

* Date of Submission:


Guide For New FSCA Report Submission



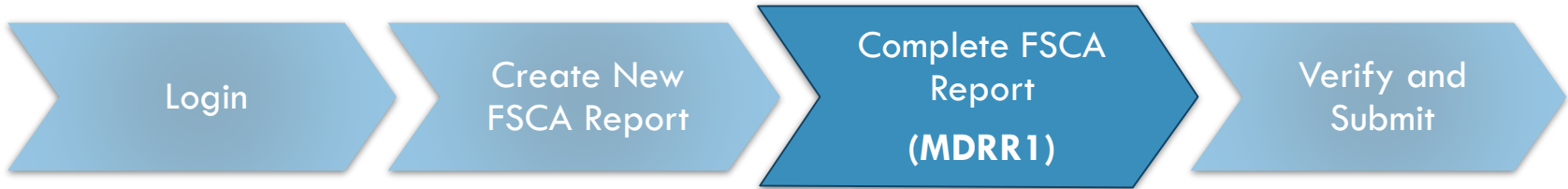
For Report Source, please indicate if the reporting company is the Importer, Wholesaler, Registrant, and/or Manufacturer of the affected devices.


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

Company Particulars

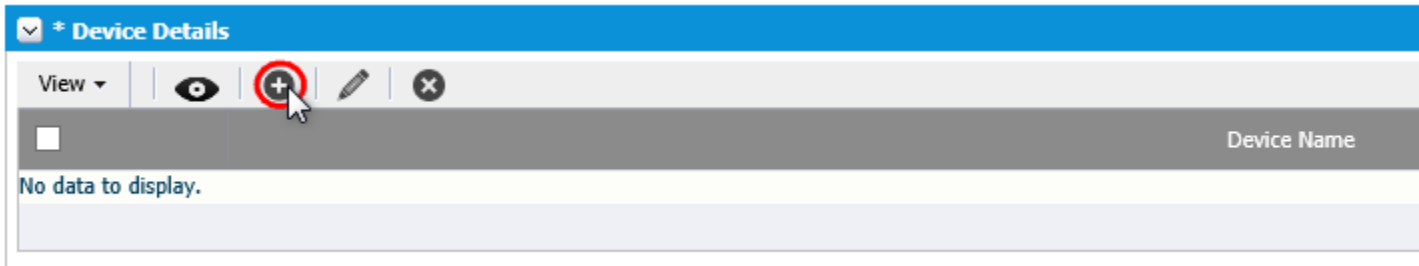
<input checked="" type="checkbox"/> Company Particulars	
* Company Name:	<input type="text" value="Test Company"/>
Company UEN:	<input type="text"/>
Report Source:	<input type="text" value="Importer, Wholesaler, Registrant, Manufacturer"/>
* Contact Person Name:	Mrs <input type="text" value="Jane"/> <input type="text" value="Tan"/>
* Job Title:	<input type="text" value="Regulatory Specialist"/>
Address Type: <input checked="" type="radio"/> Local <input type="radio"/> Foreign	
* Address:	Postal Code: <input type="text" value="138667"/> 
	Block/House No.: <input type="text" value="11"/> Level-Unit No.: <input type="text" value="01"/> - <input type="text" value="01"/>
	Building Name: <input type="text" value="HELIOS"/>
	Street Name: <input type="text" value="BIOPOLIS WAY"/>
	Country: <input type="text" value="SINGAPORE"/>
* Telephone No.:	<input type="text" value="61234567"/>
Fax No.:	<input type="text"/>
* Email:	<input type="text" value="jane@company.com"/>
* Local Telephone No.(for publication on HSA Website):	<input type="text" value="67654321"/>
Local Fax No.:	<input type="text"/>
* Local Email Address(for publication on HSA Website):	<input type="text" value="company@company.com"/>

Guide For New FSCA Report Submission

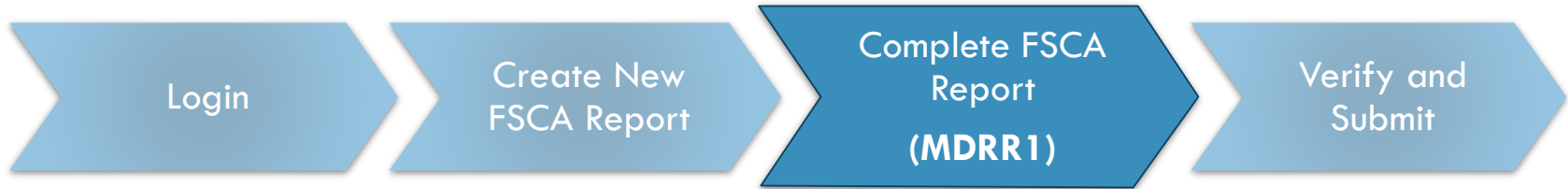



To add details of the affected device, please click on the *Add*  button.

Device Details



Guide For New FSCA Report Submission



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

Device Details

Device Details

* Status of Marketing Authorization:

* SMDR Listing No.:

* Device Name:

* Device intended use:

MD Risk Class:

Model No.:

Catalogue No.:

Serial No.:

Lot/Batch No.:

Accessories / Associated Devices affected (if any):

* Product Owner:

Address Type: Local Foreign

Postal Code:

Block/House No.: Level- Unit No.: -

Building Name:

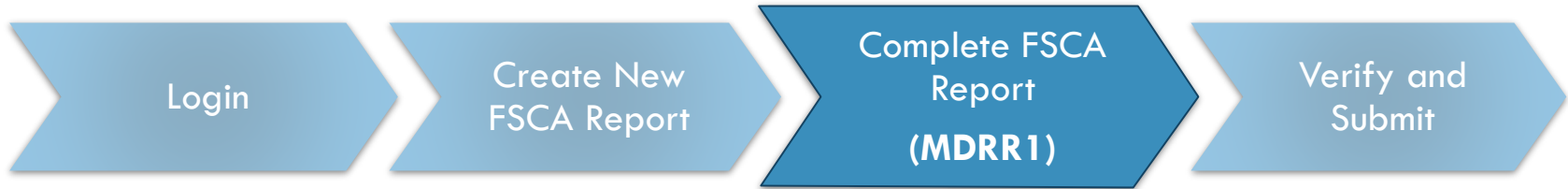
Street Name:



Country:

Upload Product Status

Alternatively, you may use this file as a template Product Status Upload File.xlsx

Guide For New FSCA Report Submission







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

Manufacturer, Wholesaler, Importer, and Registrant Information

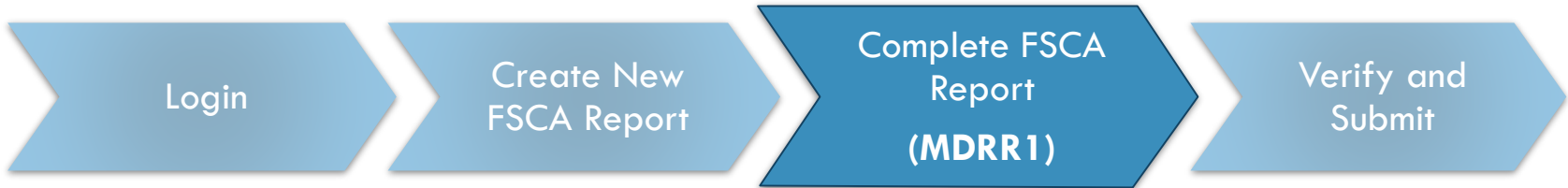
View    

<input type="checkbox"/>	Company Name	Type of Company	Contact Person Name	Job Title	Telephone No.	Fax No.	Email
No data to display.							

Save and Close

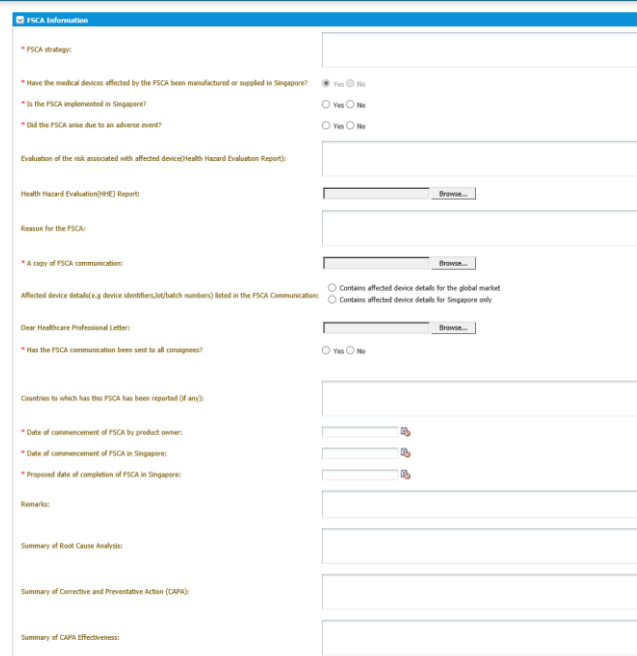
Cancel

Guide For New FSCA Report Submission



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.

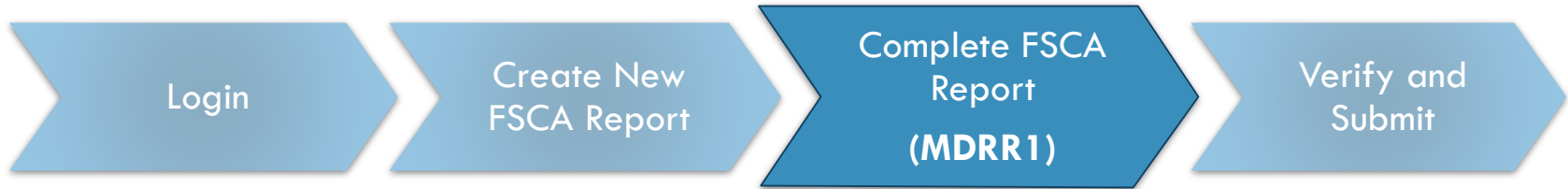
FSCA Information



FSCA Information

- * FSCA strategy: [Text field]
- * Have the medical devices affected by the FSCA been manufactured or supplied in Singapore? Yes No
- * Is the FSCA implemented in Singapore? Yes No
- * Did the FSCA arise due to an adverse event? Yes No
- Evaluation of the risk associated with affected device(s)/Health Hazard Evaluation Report: [Text field]
- Health Hazard Evaluation (HHE) Report: [Browse...]
- Reason for the FSCA: [Text field]
- * A copy of FSCA communication: [Browse...]
- Affected device detail(s)-e.g device identifiers,lot/batch numbers) listed in the FSCA Communication: Contains affected device details for the global market Contains affected device details for Singapore only
- Dear Healthcare Professional Letter: [Browse...]
- * Has the FSCA communication been sent to all consignees? Yes No
- Countries to which has this FSCA been reported (if any): [Text field]
- * Date of commencement of FSCA by product owner: [Date field]
- * Date of commencement of FSCA in Singapore: [Date field]
- * Proposed date of completion of FSCA in Singapore: [Date field]
- Remarks: [Text field]
- Summary of Root Cause Analysis: [Text field]
- Summary of Corrective and Preventative Action (CAPA): [Text field]
- Summary of CAPA Effectiveness: [Text field]

Guide For New FSCA Report Submission



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)

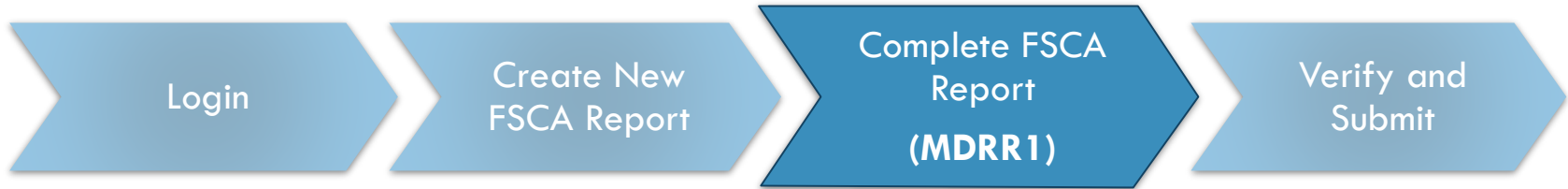
Type of change with reference to GN-21 (e.g software change, design change, labelling change):

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



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

Other Information

Other Information:

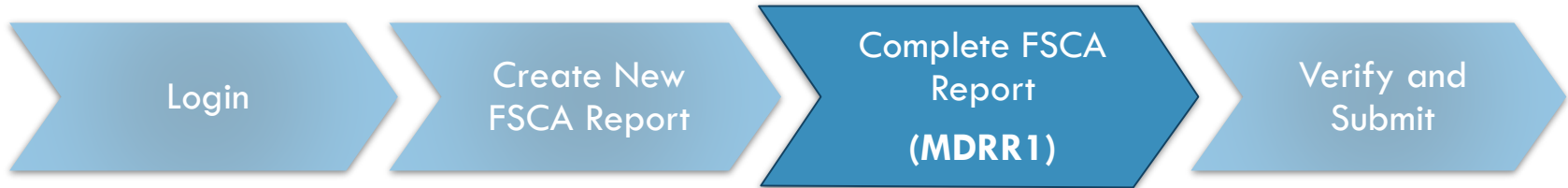
Other Attachments: Please Select

View ▾

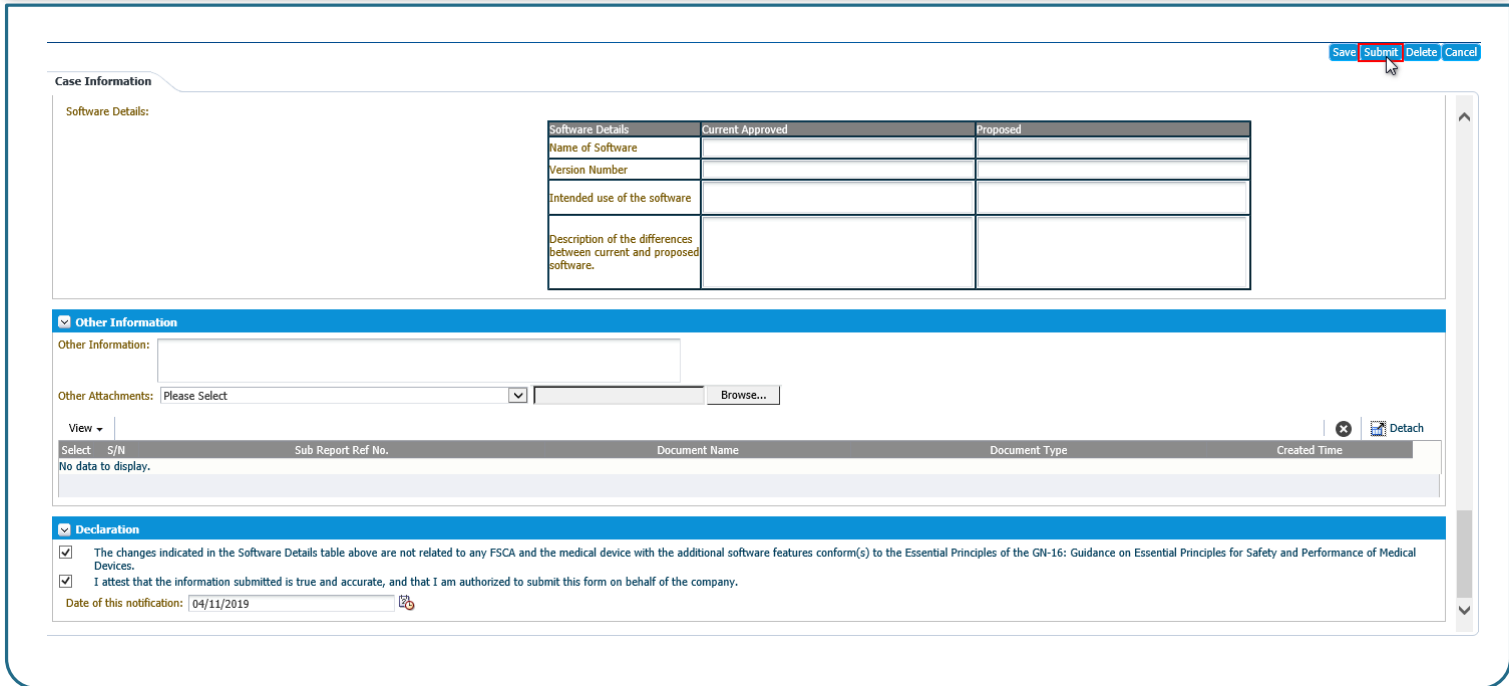
Select	S/N	Document Name
<input type="checkbox"/>		Risk Communication Letter (FSN, DHCPL etc.)
<input type="checkbox"/>		Health Hazard Evaluation (HHE)
<input type="checkbox"/>		Proposed Recall Strategy
<input type="checkbox"/>		Investigation Reports (Root cause analysis, CAPA, CAPA effectiveness)
<input type="checkbox"/>		Additional Updates
<input type="checkbox"/>		Correspondences
<input type="checkbox"/>		Other References
<input type="checkbox"/>		Product Status
<input type="checkbox"/>		Software Details - Appendix 1

No data to display.

Guide For New FSCA Report Submission



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

Case Information

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.		

Other Information

Other Information:

Other Attachments:

View

Select	S/N	Sub Report Ref No.	Document Name	Document Type	Created Time
No data to display.					

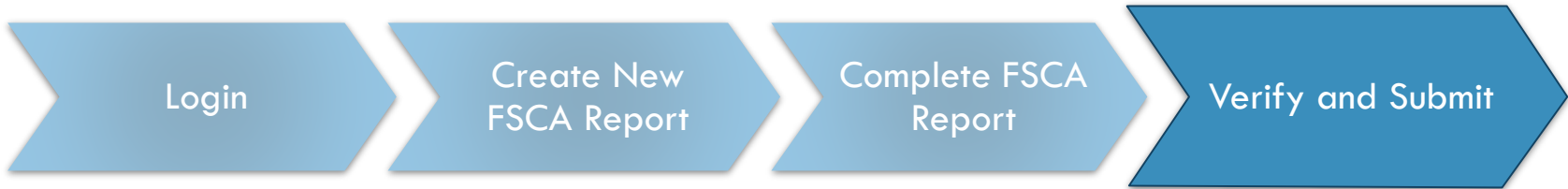
Declaration

The changes indicated in the Software Details table above are not related to any FSCA and the medical device with the additional software features conform(s) to the Essential Principles of the GN-16: Guidance on Essential Principles for Safety and Performance of Medical Devices.

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:

Guide For New FSCA Report Submission



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

A screenshot of a confirmation message dialog box. The dialog has a blue header with the text 'Confirmation Message'. Below the header, the text reads 'Are you sure you want to submit the task?'. At the bottom of the dialog, there are two blue buttons: 'Yes' and 'No'. A mouse cursor is hovering over the 'Yes' button. The dialog is centered within a larger white rectangular frame.

Guide For New FSCA Report Submission



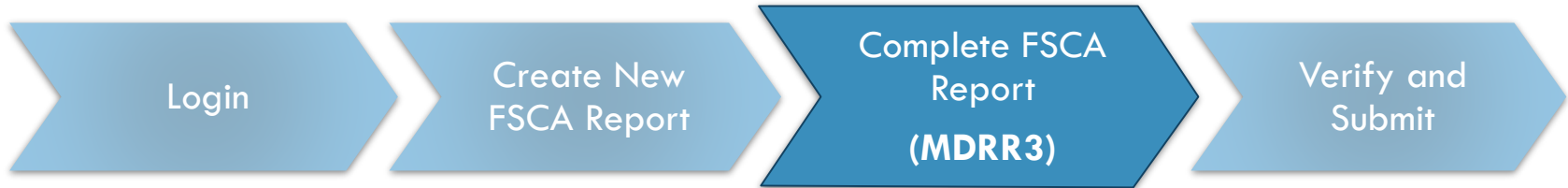
Please note down the FSCA Reference Number issued after report submission.
For communications with HSA regarding the FSCA reported, kindly quote this FSCA Reference Number.

MDRR1 submission is completed.



Your report has been submitted successfully. The FSCA Reference No. for this FSCA is **2019-FSCA-000064**. Click 'Back To Task List' Button to go back to task list.

Guide For New FSCA Report Submission



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

Case Information

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

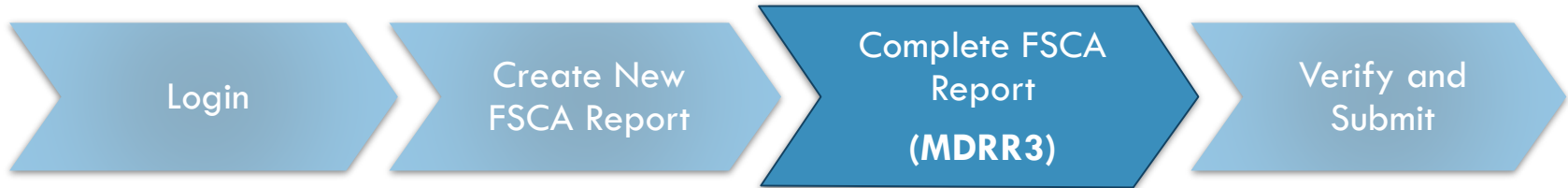
* Type of Report: Notification Report Preliminary Report Follow Up Report Final Report

* FSCA Ref No.:


* Sub Report Ref No.:

* Date of Submission:


Guide For New FSCA Report Submission



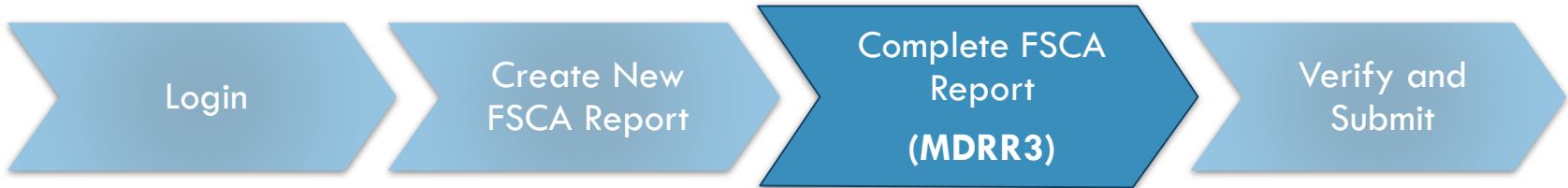
For Report Source, please indicate if the reporting company is the Importer, Wholesaler, Registrant, and/or Manufacturer of the affected devices.

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

Company Particulars

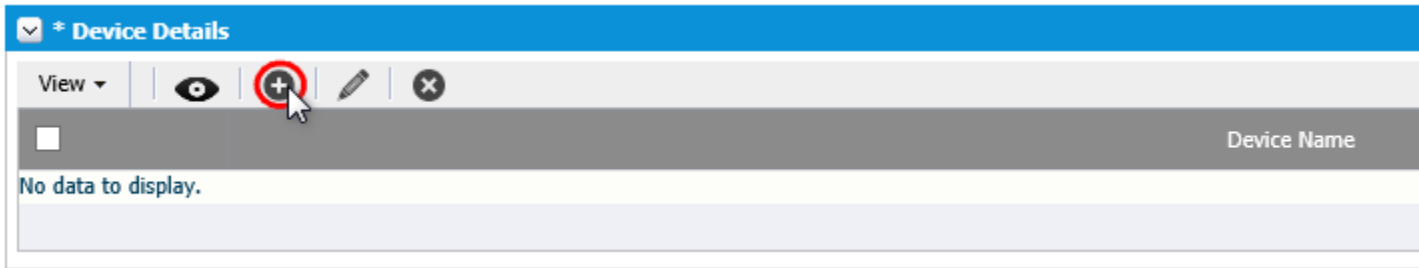
<input checked="" type="checkbox"/> Company Particulars	
* Company Name:	<input type="text" value="Test Company"/>
Company UEN:	<input type="text"/>
Report Source:	<input type="text" value="Importer, Wholesaler, Registrant, Manufacturer"/>
* Contact Person Name:	Mrs <input type="text" value="Jane"/> <input type="text" value="Tan"/>
* Job Title:	<input type="text" value="Regulatory Specialist"/>
Address Type: <input checked="" type="radio"/> Local <input type="radio"/> Foreign	
* Address:	Postal Code: <input type="text" value="138667"/> 
	Block/House No.: <input type="text" value="11"/> Level- Unit No.: <input type="text" value="01"/> - <input type="text" value="01"/>
	Building Name: <input type="text" value="HELIOS"/>
	Street Name: <input type="text" value="BIOPOLIS WAY"/>
	Country: <input type="text" value="SINGAPORE"/>
* Telephone No.:	<input type="text" value="61234567"/>
Fax No.:	<input type="text"/>
* Email:	<input type="text" value="jane@company.com"/>
* Local Telephone No.(for publication on HSA Website):	<input type="text" value="67654321"/>
Local Fax No.:	<input type="text"/>
* Local Email Address(for publication on HSA Website):	<input type="text" value="company@company.com"/>

Guide For New FSCA Report Submission

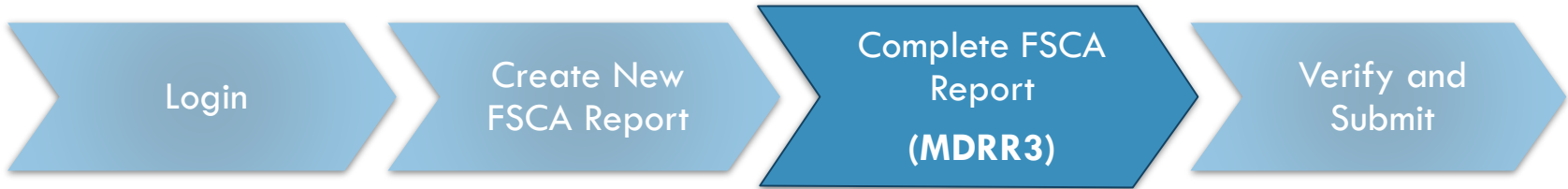



To add details of the affected device, please click on the *Add*  button.

Device Details






Guide For New FSCA Report Submission




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

Device Details

Device Details

- * Status of Marketing Authorization: SMDR 
- * SMDR Listing No.: 
- * Device Name:
- * Device intended use:
- MD Risk Class: 
- Model No.:
- Catalogue No.:
- Serial No.:
- Lot/Batch No.:
- Accessories / Associated Devices affected (if any):
- * Product Owner:

Address Type: Local Foreign

Postal Code: 

Block/House No.: Level- Unit No.: -

Building Name:

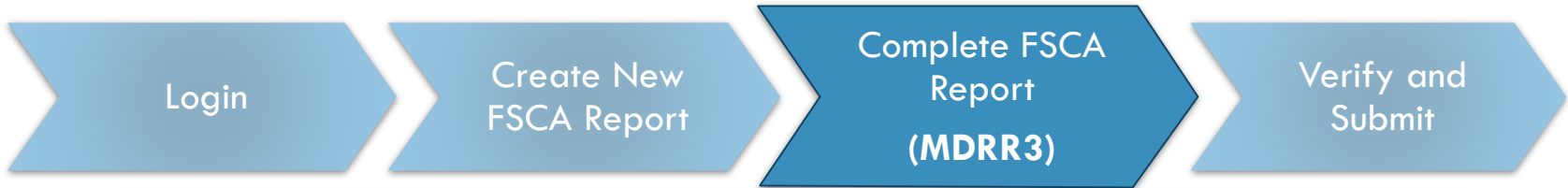
Street Name:

Country: SINGAPORE

Upload Product Status

Alternatively, you may use this file as a template Product Status Upload File.xlsx

Guide For New FSCA Report Submission







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

Manufacturer, Wholesaler, Importer, and Registrant Information

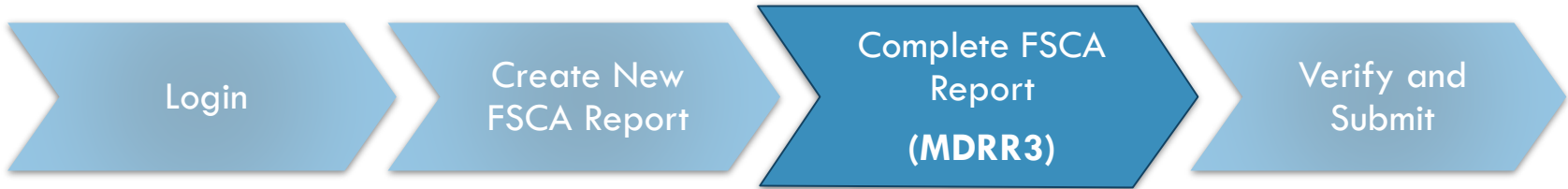
View    

<input type="checkbox"/>	Company Name	Type of Company	Contact Person Name	Job Title	Telephone No.	Fax No.	Email
No data to display.							

Save and Close

Cancel

Guide For New FSCA Report Submission



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

Medical Device Post-Market Information

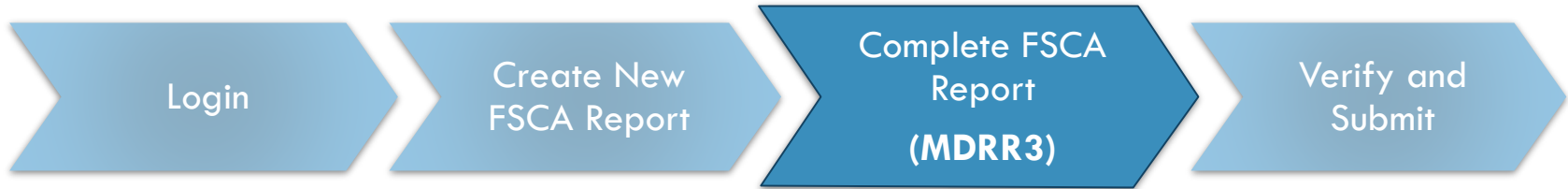
Medical Device Post-Market Information:

Type of Post-Market Information

- Field Safety Corrective Action (FSCA)
- Medical Device Complaint Record
- Product Defect other than FSCA
- Others

If Others, please specify:

Guide For New FSCA Report Submission



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

FSCA Information

FSCA Information

* Have the medical devices affected by the FSCA been manufactured or supplied in Singapore? Yes No

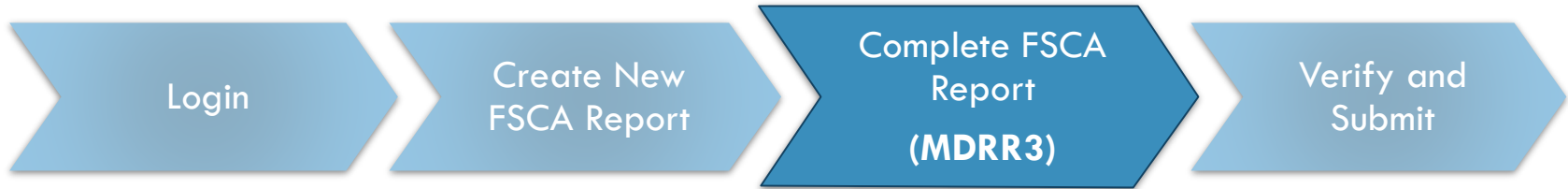
*If yes, please report using the MDRR1 report form instead.

* A copy of FSCA communication:

Remarks

Date of commencement of FSCA by product owner:

Guide For New FSCA Report Submission



If applicable, complete the product defect/complaint information section

Product Defect or Complaint Information

Medical Device Product Defect or Complaint Information (Where applicable)

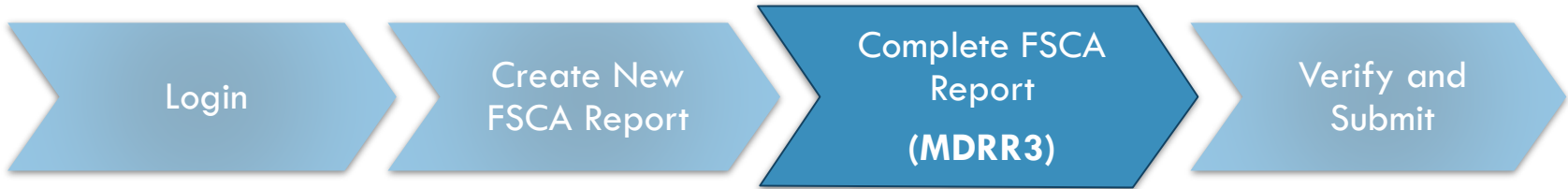
Description of Product Defect or Complaint:

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



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.

Case Information

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:

Other Information

Other Information:

Other Attachments: Please Select

Select	S/N	Sub Report Ref No.	Document Name	Document Type	Created Time
No data to display.					

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.
- Prior to any future supply of devices corrected of this FSCA, I will verify if a change notification (CN) submission through MEDICs is required. If MEDICs CN submission is required, new supply of devices corrected of this FSCA shall not proceed unless prior approval from HSA has been received.
- I declare that any new supply of devices corrected of this FSCA shall not be defective and shall conform to the Essentials Principles of the GN-16: Guidance on Essential Principles for Safety and Performance of Medical Devices, and any other applicable regulatory requirements.

Date of this notification:

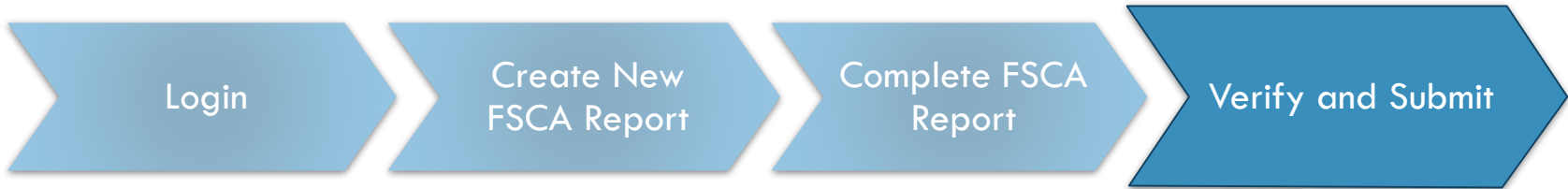
Guide For New FSCA Report Submission



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



Guide For New FSCA Report Submission



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.



Your report has been submitted successfully. The FSCA Reference No. for this FSCA is **2019-FSCA-000064**. Click 'Back To Task List' Button to go back to task list.

END



Updated as of July 2021