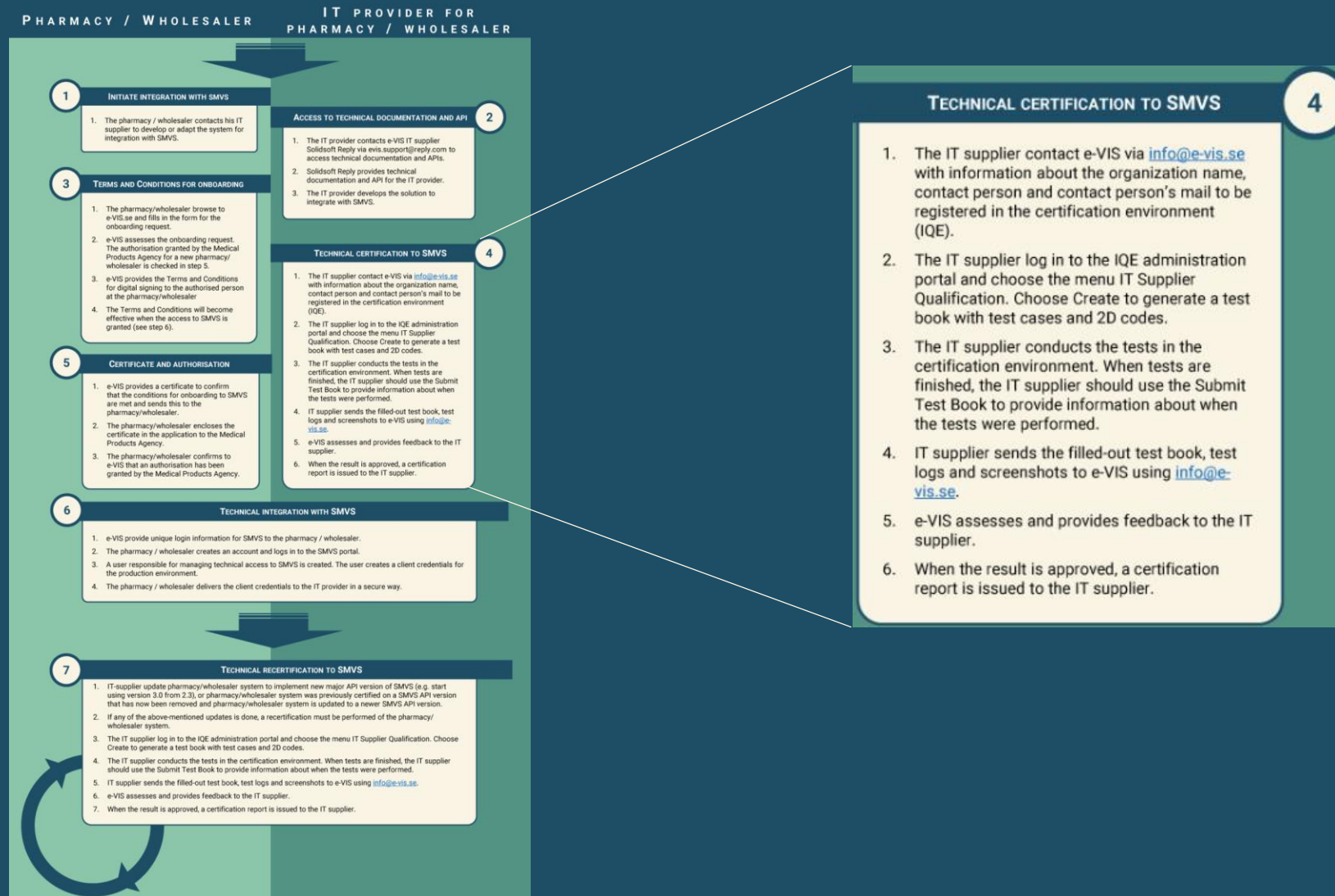


Technical certification and recertification of systems integrating to SMVS

Onboarding process – Technical certification



WHY is certification needed?



- The EMVS is a complex system and to facilitate and help end-users to correctly integrate and use the system, a certification process is in place by e-VIS.
- The technical certification is performed by the end-users IT-supplier, but it is the end-user that must ensure that the system in use is integrated to SMVS in a correct way, working as expected and is compliant to the Delegated Regulation and e-VIS Terms and Conditions.
- The number of technical “false” alerts in Sweden are relatively low, but there are still some problems with end-user scanners/software. To increase the possibility to identify these problems and prevent them to reach the end-user production systems the certification process also include recertification.
- Changes are continuously made in the SMVS and EMVS system. New API versions will be available and old API versions will be deprecated and removed. The end-users need to ensure that their systems are up-to-date and compliant to the Delegated Regulation and therefore recertification of existing solutions is needed.

WHEN is certification needed?



- Before an end-user (pharmacy or wholesaler) can connect their system to SMVS the IT-supplier of the end-user system needs to perform and get an approved technical certification of the end-user software. The certification is performed using the SMVS Integrated Qualification Environment (IQE).
- A certification performed on the Swedish IQE is needed for all IT-suppliers that have end-users on the Swedish market. This means that an approved certification report from other countries is not valid as proof.
- When an end-user system is updated and starts using a new MAJOR version of the SMVS API (e.g. going from version 2.4 to 3.0) a recertification should be initiated by the IT-supplier.
- The end-user system was previously certified on an API version of SMVS that is no longer used, and the end-user system must use a newer API version of SMVS.
- A certification report is issued to the IT-supplier following an approved certification/recertification.

WHEN is certification needed?



NOTE!

Recertification is NOT mandatory if the IT-supplier implements new update of the end-user software without making changes in the integration to the SMVS.

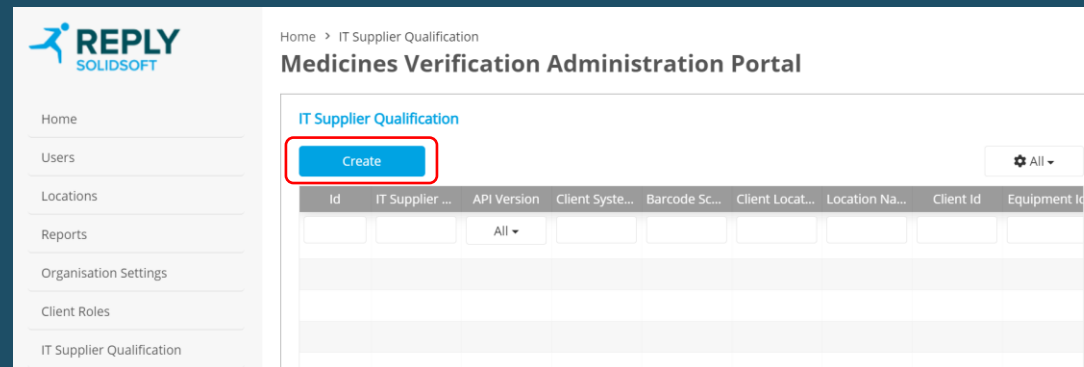
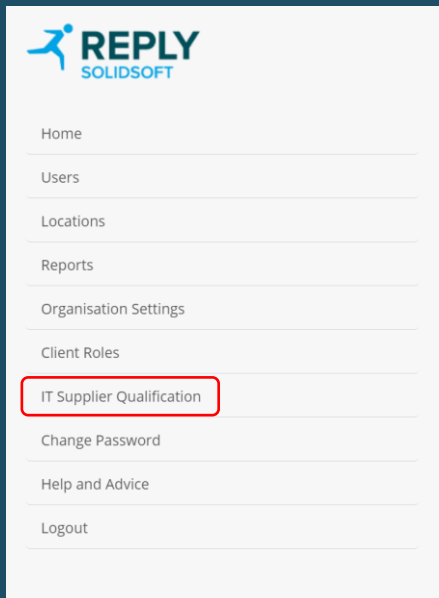
BUT,

e-VIS strongly recommends that regression tests are executed using the Qualification Test Book before every release to validate that the updated software is still working as expected and is compliant to the Delegated Regulation. The voluntary use of the test book is a way of ensuring a correct implementation to SMVS and is also providing for the documentation that these quality measures have been taken.

HOW is the certification performed?



- The technical certification is initiated by the end-user IT-supplier by first requesting access to Integrated Qualification Environment (IQE) from e-VIS (if not having access already) using info@e-vis.se.
- The IT supplier log in to the IQE admin portal (<https://portal-se-iqe.nmvo.eu/>) and first choose the menu IT Supplier Qualification, and then choose Create to generate a test book with test cases and 2D codes.



HOW is the certification performed?



- The IT supplier perform the tests in the IQE environment. All tests are not mandatory to perform and can be disregarded/skipped (e.g., bulk transactions) if the software does not support the functionality. The relevant test steps performed by the IT-supplier are documented in the Qualification Test book together with some general IT-supplier information.
- The mandatory test steps for a **pharmacy** system are:
 - Verification of packs (Test Case ID: 01 BULK VERIFY and/or Test Case ID: 05 SINGLE VERIFY)
 - Supply packs (Test Case ID: 02 BULK SUPPLY and/or Test Case ID: 06 SINGLE SUPPLY)
 - Destroy packs (test step 2 in Test Case ID: 04_BULK_DECOMMISSION and/or test step 1 in Test Case ID: 08_SINGLE_DECOMMISSION)
 - Reactivate packs (Test Case ID: 03 BULK REACTIVATE and/or Test Case ID: 07 SINGLE REACTIVATE)
- The mandatory test steps for a **wholesaler** system are:
 - Verification of packs (Test Case ID: 01 BULK VERIFY and/or Test Case ID: 05 SINGLE VERIFY)
 - Destroy packs (test step 2 in Test Case ID: 04_BULK_DECOMMISSION and/or test step 1 in Test Case ID: 08_SINGLE_DECOMMISSION)

HOW is the certification performed?



- When testing is done, the IT-supplier use the Submit Test Book in IQE Admin portal to provide information about when the tests were performed.

The screenshot shows a table titled "IT Supplier Qualification" with a "Create" button and a "Filtered" dropdown. The table has columns for Id, IT Supplier, API Version, Client System, Client Location, Location Name, Equipment Id, Template Version, Created Date, Completed Date, Start Date of, End Date of, Test Book Status, and Actions. A single row is visible with the following data: SE_1, e-VIS, 3.0, PostmanRu..., 25074338-c..., eVIS_Office1, 1, 3.0, 2023-09-01 ..., and Active. The Actions column contains icons for edit, refresh, and delete, with the delete icon highlighted by a red square.

Id	IT Supplier ...	API Version	Client Syste...	Client Locat...	Location Na...	Equipment Id	Template V...	Created Dat...	Completed ...	Start Date o...	End Date of...	Test Book S...	Actions
SE_1	e-VIS	3.0	PostmanRu...	25074338-c...	eVIS_Office1	1	3.0	2023-09-01 ...				Active	

- IT supplier sends the filled-out Qualification test book, IT-supplier log file and screenshots to e-VIS using info@e-vis.se.
- e-VIS assess the tests, and a certification report is issued following an approved certification for the functionality that has been tested.

IQE Qualification Test Book



- The Qualification Test Book consist of different tests and test steps that are created to find common problems in the implementation.
- 13 basic integration test flows are included:
 - 4 test flows for Bulk API excluding alert testing (**optional** if not used in end-user software)
 - 4 test flows for basic functionality in Single Pack API (some are mandatory)
 - 4 test flows for testing of known and common problems in Single Pack API (most are mandatory)
 - 1 test flow for Reporting API (Optional if not used in end-user software)

IQE Qualification Test Book




General supplier information

2.5 IT Supplier Information	
IT Supplier Name	<Enter IT Supplier Name>
IT Supplier Test Manager Contact	<Enter Test Manager Contact>
Environment Tested Against	<marketCode> IQE
Client System Build/Version Number	<Enter Build/Version Number>
Barcode Scanner Model	<Enter Barcode Scanner Model>
Start and End Time of Testing	<Enter Start and End Date/Time>
Client Location ID	<Enter Client Location ID>
Client ID	<Enter Client ID>
Client Equipment ID	<Enter Client Equipment ID>
National System API Version	<APIVersion>

Software Provider Certification Report




Report Date: YYYY-MM_DD

IT Software Provider Certification Report		
IT Software Provider Information		
Name of IT Software Provider	<IT Software Provider name>	
Name of IT Supplier Test Manager	<IT Supplier Test Manager name>	
Name of system tested and version number	<Name of system and version>	
Tested SMVS API version	<Tested version>	
Test documentation received		
EMVS National Blueprint System Qualification Test Book completed	<input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
Screenshots completed and attached	<input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
e-VIS Assessment and approval ¹		
Result of IT Software Provider Assessment		
<input type="checkbox"/> All test cases were passed, and System is approved to connect to SMVS	Comment:	
<input type="checkbox"/> All test cases that were executed passed ² and system is approved to connect to SMVS	Test cases tested:	
	Test cases not tested:	
	Comment:	
<input type="checkbox"/> Tests not passed and system is not approved to connect to <u>SMVS</u>	Reason:	
Details of e-VIS approver		
Name		
Job title		
Date of Approval		
Signature		

¹ **Disclaimer:** Passing the self-certification tests demonstrates that the System is correctly connected to the SMVS but e-VIS has not reviewed the System's features or functionality. If specific test cases have not been executed, e.g. Bulk of Pack tests, the System is not approved to connect to the SMVS in respect of the relevant activity. End-Users must assure themselves that any system they utilise to verify and decommission medicines meets their specific workplace requirements.

² The IT Software Provider has opted not to execute specific test cases in the Test Book on the basis they are not applicable to their System.

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