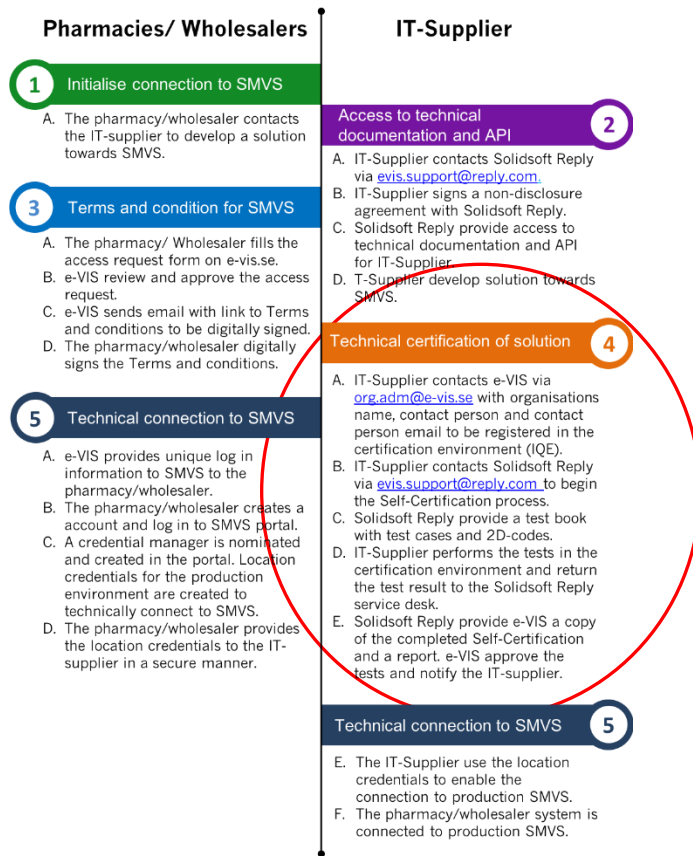


Technical certification and recertification of systems integrating to SMVS

Current onboarding process



**Technical certification valid until
August 2020**

1/2 Current Technical Certification process

– as of August 2020

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 IQE environment.

An approved certification could either be:

- IT-supplier certification performed using a baseline test book provided by e-VIS IT-supplier (Solidsoft Reply). All tests are not necessary to perform and can be disregarded/skipped (e.g. bulk transactions) if the software does not support the functionality. e-VIS provides a signed certification report as proof to the end-user IT-supplier.

OR

- IT-supplier certification approved in another country using the same IT-supplier as e-VIS, i.e. Solidsoft Reply, and a signed certification report is provided as proof.

2/2 Current technical certification process – as of August 2020

IQE Test book

- 8 basic integration test flows with a few test steps that test different aspects of the system, e.g. different types of errors and alerts.
 - 4 test flows for Single Pack API
 - 4 test flows for Bulk API (optional if not used in end-user software)
- Test result documented
 - Test result log
 - Screenshots pasted in test result from tests that generate warning or alert

New Technical certification and recertification valid from September 2020

New technical certification process – WHY is certification needed?

The EMVS is a complex system and in order to facilitate and help end-users to correctly use the system, a certification process is in place.

The regulation has been in force since 9th of February 2019 and since then a lot of knowledge about known/common problems when integrating to the SMVS has been gained.

The number of technical “false” alerts in Sweden are getting lower, but there are still some problems with end-user scanners/software. To increase the possibility to identify these problems and prevent these (and other) defects to reach the end-user production systems the certification process is updated to also include **recertification**.

Changes are continuously made in 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 e-VIS therefore foresee that recertification of existing solutions is needed.

1/3 New technical certification process – WHEN to recertify

When an end-user system is updated and in order to start using a new MAJOR version of the SMVS API (e.g. going from version 1.5 to 2.1) a recertification should be initiated.

The technical certification is performed by the end-user IT-supplier, but it is the end-user that needs to ensure that the system in use is integrated to SMVS in a correct way, working as expected and compliant to the Delegated Regulation and e-VIS Terms and Conditions.

A certification report is issued following recertification.

2/3 New technical certification process – WHEN to recertify

A certification to SMVS 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 no longer valid as proof. e-VIS is adopting this approach in alignment with other countries using same IT-supplier as e-VIS, i.e. Solidsoft Reply.

3/3 New technical certification process - WHEN to recertify?

NOTE!

Recertification is not mandatory if the IT-supplier implements new major 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.

New technical certification process – HOW to certify?

The updated IQE Test book (renamed to **Qualification** Test Book) can be used to find common problems in the implementation:



- 8 basic integration test flows are still included but with some small changes to be more specific:
 - 4 test flows for Single Pack API excluding alert testing
 - 4 test flows for Bulk API excluding alert testing (**optional** if not used in end-user software)
- 4 tests areas:
 - Alerts
 - Manual entry
 - Character set
 - Reports (**optional**)
- IT Supplier information that should be submitted have been extended to also include:
 - Location ID, Client ID, Client Equipment ID, Barcode Scanner Model
- Screenshots should be attached instead of pasted into test book
- Test result log still available

Examples from the Qualification Test Book

Updated test book – Test cases

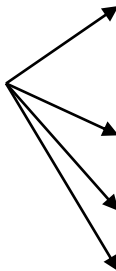
3.5.1	Test Case ID: 01_BULK_VERIFY: NBS/E2E/Bulk Pack/Verify	9
3.5.2	Test Case ID: 02_BULK_SUPPLY: NBS/E2E/Bulk Pack/Supply	11
3.5.3	Test Case ID: 03_BULK_REACTIVATE: NBS/E2E/Bulk Pack/Reactivate	13
3.5.4	Test Case ID: 04_BULK_DECOMMISSION: NBS/E2E/Bulk Pack/Decommission	15
3.5.5	Test Case ID: 05_SINGLE_VERIFY: NBS/E2E/Single Pack/Verify.....	17
3.5.6	Test Case ID: 06_SINGLE_SUPPLY: NBS/E2E/Single Pack/Supply	19
3.5.7	Test Case ID: 07_SINGLE_REACTIVATE: NBS/E2E/Single Pack/Reactivate	20
3.5.8	Test Case ID: 08_SINGLE_DECOMMISSION: NBS/E2E/Single Pack/Decommission.....	22
3.5.9	Test Case ID: 09_ALERTS: NBS/E2E/Single Pack/Alerts	23
3.5.10	Test Case ID: 10_MANUAL: NBS/E2E/Single Pack/Manual Entry	25
3.5.11	Test Case ID: 11_CHARACTER SET: NBS/E2E/Single Pack/Character Set.....	27
3.5.12	Test Case ID: 12_REPORT: NBS/Report API.....	28

3.5.5 Test Case ID: 05_SINGLE_VERIFY: NBS/E2E/Single Pack/Verify

Test Step	Expected Result
1. Attempt to VERIFY the following pack:	
Product Code GTIN: Serial Number: Batch ID: Expiry Date: Initial Public Pack State: Active	 User receives the following message: 200 OK <pre>{ "operationCode": "11110100", "state": "Active", "information": "The pack is available to be dispensed." }</pre>
2. Attempt to VERIFY the following pack:	
Product Code GTIN: Serial Number: Batch ID: Expiry Date: Initial Public Pack State: Supplied	 User receives the following message: 200 OK <pre>{ "operationCode": "11110200", "state": "Supplied", "information": "The pack has been supplied." }</pre>

Updated test book – IT Supplier information

New fields



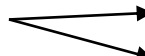
IT Supplier Name	<Enter IT Supplier Name>
IT Supplier Test Manager Contact	<Enter Test Manager Contact>
Environment Tested Against	<Enter Environment Name>
Client System Build/Version Number	<Enter Build/Version Number>
Barcode Scanner Model	<Enter Barcode Scanner Model>
Start and End Time of Testing	<Enter Time>
Client Location ID	<Enter Client Location ID>
Client ID	<Enter Client ID>
Client Equipment ID	<Enter Client Equipment ID>

Updated Software Provider Certification Report



Report Date: YYYY-MM-DD

New fields



IT Software Provider Certification Report		
IT Software Provider Information		
Name of IT Software Provider		
Name of IT Supplier Test Manager		
Name of system tested and version number		
Tested SMVS API 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 SMVS	Reason:	
Details of e-VIS approver		
Name	<name>	
Job title	e-VIS Operations Manager	
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.



Failed tests, failed certification and way forward

1/2 New technical certification process – Failed tests

What happens if some tests fail?

- The qualification tests are testing the core functionality and e-VIS opinion is that all test cases (if the functionality is used in the end-user software) should be successfully performed for an approved certification.
- Only exception to this is Report tests which are optional and don't raise alerts if not properly used.

2/2 New technical certification process – Failed tests

In case of emergency (e.g. failed tests and certification, but need to deploy for other reasons), please contact e-VIS to have a discussion about the situation.

A risk assessment should be performed with the involved and relevant parties to see and define if the software can be certified with known defects or if something needs to be fixed before approved certification.

New technical certification process

– Problems with end-user software

- What kind of problems might lead to further measures taken by e-VIS?
 - Problems that immediately and substantially endangers the security or functioning of the SMVS or EMVS.
 - Problems that is in breach of the Terms & Conditions but not immediately and substantially endangers the security or functioning of the SMVS or EMVS, and the breach is not fixed within 90 calendar days after been communicated to end-user in writing by e-VIS.
- What happens?
 - e-VIS to have a dialogue with the end-user and end-users IT-supplier to identify, analyse and plan how to fix the problems.
 - Involve the MPA (Läkemedelsverket) in the dialogue if needed.

New technical certification process

– Problems with end-user software

- In worst case, where no other option is available, the end-user organisation could be disconnected from SMVS.
 - No verification or supply of packs in the EMVS can be performed.
- A disconnection is made on organisation level meaning that not only a specific location is suspended but ALL locations for the organisation that have been set up in SMVS Portal are disconnected.

Tips & Tricks

New technical certification process – Tips & Tricks

1. Perform regression test using the Qualification Test Book when your IT-system changes. Finding defects/problems before your new release goes to production will save you and the pharmacists scanning packs time in the long run.
2. Use the same scanners when performing tests and certification that are used by end-users. Some problems are solely based on scanner issues/scanner models. Testing as production like as possible should also cover scanner models.
3. Use scanners when performing tests and certification with known complexity (that is known to cause problems).
4. Perform tests using the new test book when adding and testing new scanner model. See bullet number 1.
5. If running into problem. Don't hesitate to contact e-VIS. Again – presenting defects going into production environment save time and resources for all parties in the medicinal product distribution chain.