

EMVS3542 NMVS Self Service Qualification Testbook Guide for IT Suppliers

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Audience: IT Suppliers for Pharmacies, Wholesalers, Hospitals

Revision History

* [Complete Revision History](#) can be found within the appendix.

Document Approval

Name	Role/ Title	Signature	Date	Meaning of Signature
David Joyce	Author	<u>DJoyce</u> DJoyce (Mar 6, 2025 17:32 GMT)	Mar 6, 2025	I am signing to certify this document has been produced following the prescribed process and that it meets technical requirements.
Steven Sloggett	Development Lead	<u>S. Sloggett</u>	Mar 6, 2025	I am approving this document to clarify that it meets technical requirements.
Rizwan Rehman	Project Manager	<u>Rizwan Rehman</u> Rizwan Rehman (Mar 6, 2025 16:46 GMT)	Mar 6, 2025	I am approving this document to certify that it meets business requirements.
Matt Stellmacher	Senior CSV Consultant	<u>Matt Stellmacher</u> Matt Stellmacher (Mar 6, 2025 17:31 GMT)	Mar 6, 2025	I am approving this document to certify that it meets quality and compliance requirements.

*Note that date will be automatically added by the electronic signing tool. If signing by hand, please include date. If date and time are not shown under electronic signatures, the audit trail at the back of this document shows the date and time of signature.

Self Service QTB User Guide for IT Suppliers

Introduction

This User Guide provides guidance to IT Suppliers of Pharmacies, Wholesalers, and Hospitals on the usage of the National Medicines Verification System to manage the creation and execution of Test Books for their client(s). The examples used in the slides may present data specific to a Wholesaler account, or a Pharmacy account, but all processes and features are equally applicable to the above organisation types.

Terminology

National Medicines Verification Organisation (NMVO)

The organisation set up by national stakeholders to manage the National System and medicine verification for that country

National Medicines Verification System (NMVS)

A system in the European Medicines Verification landscape that serves as the verification platform for one country. Local Organisations check a product's authenticity using a connection to this system

Local Organisations

The organisations required to use the NMVS to check a product's authenticity (Pharmacy or Wholesaler),

Users

- A User of the system is a physical user, i.e. a person.
- A User interacts with the NMVS through the NMVS Administration Portal and the NMVS Emergency Verification Portal.
- A User requires an NMVS account to login to the Administration Portal.
- Users for the IT Supplier will be setup with appropriate User Role with all necessary permissions ("Qualification Testing/Control") to perform their role.

IT Supplier Qualification

The purpose of the Qualification Test Book (the 'test book') is to provide a set of test cases to be executed by IT Suppliers to support qualification of their systems. Following successful qualification, the IT Supplier may connect their system to their National Medicines Verification System (NMVS).

IT Supplier Qualification - Environment



The test book will be generated for a specific NMVS Integrated Quality Environment (IQE) market. The test book can only be used for the intended market in which the associated data has been generated. The API endpoints of the intended market where the test book has been generated can be found in section 2.1 on the test book and the [endpoints page](#) within the ITE Developer Portal.

The IT Supplier Qualification Test Book can be self-service generated via the IQE NMVS Administration Qualification Test Book page. Links to the NMVS Administration Portal can also be found on the endpoints page linked above. The functionality to generate and manage IT Supplier Qualification Test Books must be assigned to a local organisation, this authorisation is provided by the NMVO. If your organisation is unable to navigate to the Qualification Test Book page within the NMVS Administration Page please contact the NMVO.

2. Qualification Test Guidance

2.1 Environment

This test book has been generated for the xx NMVS Integrated Quality Environment (IQE). The client solution must consume the following endpoints:

Authorization Endpoint	https://api-xx-iqe.nmvo.eu/identity/connect/token
Pack API Endpoint	https://api-xx-iqe.nmvo.eu/verification/
Reporting API Endpoint	https://api-xx-iqe.nmvo.eu/report/

Please note the following market specific configuration values, these will be used during the testing phase to determine the expected response from certain scenarios. At the time of the test book generation the NMVS environment has been configured with the following values:

- *Double Dispense Limit:* 9
- *Double Dispense Time Limit:* 10.00:00:00
- *AMS Link (ignore if empty):* https://app.example-ams.com/AlertDetails.aspx?id={{uprcToken}}

Please refer to section 2.6.2 for further information about expected result variations and the market specific configuration values.

Home > IT Supplier Qualification

Medicines Verification Administration Portal

IT Supplier Qualification

Create

All ▾

ID	IT Supplier ...	API Version	Client Syste...	Barcode Sc...	Client Locat...	Location Na...	Client Id	Equipment Id	IT Supplier ...	IT Supplier ...	Te...	Created Da...	Cr	Start Date o...	End Date of...	Test Book S...	Actions
		All ▾														All ▾	
xx_127	DST Clarke ...	3.0	9	Kofax 2000	8c950dc4-4...	Test Locati...	pharmacycl...	pharmacycl...	andy.lamon...	Andrew La...	3.	14/03/2024 ...				Active	
xx_126	Example Su...	3.1	2.0.1b	Kofax 2000	8c950dc4-4...	Test Locati...	a37cc20a-4...	Equipment ...	test.manag...	Example Co...	3.1	14/03/2024 ...	14/03/2024 ...	14/03/2024 ...	Review		

IT Supplier Qualification



IT Supplier Qualification - Portal

NOTE: IT Supplier Qualification functionality is only available on IQE.

Action to create a new test book

Home > IT Supplier Qualification

Medicines Verification Administration Portal

IT Supplier Qualification

[Create](#)

Columns can be shown / hidden using column selector

Rows in the Test Book table can be filtered according to the data in them.

Filtered

Barcode Sc...	Scanner Connec...	Client Loc...	Location...	Client Id	Equipment Id	IT Supplier ...	IT Supplier ...	Templa...	Created Da...	Submitted Date & Time...	Test Book S...	Actions
Kofax 2000	USB COM Port E...	8c950dc4-...	Test Loc...	a37cc20a-4...	Equipment ...	a.lamont@...	Andrew La...	5.0	24/01/2025 ...		Active	
Kofax 2000	Keyboard Wedg...	8c950dc4-...	Test L...			Andy Lamont	6.0		24/01/2025 ...	24/01/2025 15:22:18	Review	

5 rows

Test Book status can be one of:

- Active
- Certified
- Failed
- Review
- Revoked

Active – the default state for a test book. Testing can be performed while the test book is Active. Test data resets can be performed while Active.

Certified – testing has been completed and the NMVO has reviewed and certified the outcome of the test book.

Failed – testing has been completed and the NMVO has reviewed and considered the outcome and deemed the testing to have failed.

Review – the NMVO is reviewing the test evidence after submittal by the IT Supplier.

Revoked – when a previously certified test book has its certification revoked.

The IT Supplier Qualification page will display the following columns:

- Qualification Testbook Id
- IT Supplier Name
- API Version
- Client System Build/Version Number
- Barcode Scanner Model
- **Scanner Connection Mode**
- Client Location Id
- Location Name
- Client Id
- Equipment Id
- IT Supplier Test Manager Contact Email
- IT Supplier Test Manager Contact Name
- Template Version
- Created Date (UTC)
- Completed Date (UTC)
- Start Date of Testing (UTC)
- End Date of Testing (UTC)
- **Submitted Date & Time (UTC)**
- Test Book Status
- Actions

Actions

Manage Test Evidence

View submitted test evidence by the IT against a test book that is not Active.

Download a Test Book

Downloads the docx. generated Qualification Test Book.

Reset Test Data

Allows the IT supplier to reset the test data for an Active test book.

Submit Test Book

Clicking this button will open the submit test book. The IT supplier can upload supporting test evidence. Finalising a submittal will move the test book from Active to Review.

Delete Test Book

Allows the IT supplier to delete a test book. This option is available on Active, Failed and Revoked test books.

A row is created for each generated test book containing the unique ID of the test book as well as the IT supplier information provided when the test book was generated.

It also contains dates and times of when the testing was performed as well as when the test book was generated.

The state of the test book can also be viewed here.

IT Supplier Qualification – Create

The IT Supplier will be required to submit the following information within section 2.5 of their generated test book. The majority of this information will be requested at the point of self-service generation of a test book and will be automatically added to the generated test book. At the point of submitting the test book please ensure that this section is completed and the information provided is correct.

- IT Supplier name* – name of supplier performing the testing.
- IT Supplier test manager contact email* – the contact email address of the manager performing the testing.
- IT Supplier test manager contact name* – the contact name of the manager performing the testing.
- Environment Tested Against – the national market IQE that testing is being performed against. This information will be automatically generated.
- Client System Build/Version Number* – the name and version of the IT supplier software. The same information should be used to populate the 'User-Agent' HTTP header when the IT supplier software performs any kind of transaction against the NMVS. This may be used to check if the software being used is the same as that which was certified, and to identify if any issues are related to a specific client type.
- Barcode Scanner Model* – the vendor and model of the barcode used for testing.
- Scanner Connection Mode* – the method of connection for which the scanner connects to the computer. I.e. BT, USB, HID Keyboard, Keyboard Wedge, Serial port, etc. See Integrating Scanning Hardware for more details.
- Start and End Time of Testing – the time when the testing was performed, this will be used by Solidsoft Reply operations to extract transaction logs for the testing activity. This information shall be updated by the IT supplier and provided as part of evidence when submitting the test book for review. NOTE: when submitting the test book, both timestamps have to be selected in the UTC time-zone, and NOT in the local time-zone. If the correct time frame is not provided, the logs automatically extracted by the NMVS will not contain all the necessary information for the NMVO to assess the testing activity performed.
- Client Location ID* – testing site (e.g. test pharmacy, test warehouse etc.) used to perform the transactions. Used by the system to extract transaction logs for the testing activity.
- Client ID* - Client equipment within the selected Location, used to perform the transactions. This is required for direct connections to the NMVS, while it should be left blank if the transactions are conveyed to the NMVS via a connector.
- Client Equipment ID* – Friendly name of the client equipment selected. As for the Client ID, it should be left blank if the IT supplier software is connecting to the NMVS via a connector.
- National System API Version* – version of the API used to integrate with the National System, specified by the "emvs-api-version" HTTP header in the requests (e.g. 3.0). This will be set based on the API version of the requested test book. Note that the generated test-book is dependent on the chosen API version, e.g. they might contain a slightly different set of tests, with different expected outcomes.

Information with an * shall be provided at the point of generating the test book. This information shall be inserted automatically into section 2.5 of the generated test book.

Create Qualification Test Book ✕

* IT Supplier Name

* IT Supplier Test Manager Contact Email

* IT Supplier Test Manager Contact Name

* Client System Build/Version Number

* Barcode Scanner Model

* Scanner Connection Mode

* Client Location Id

* Client Id

* API Version

2.5 IT Supplier Information

IT Supplier Name	Example Wholesaler
IT Supplier Test Manager Contact Email	example@example.com
IT Supplier Test Manager Contact Name	Example Manager
Environment Tested Against	xx IQE
Client System Build/Version Number	FMD Solution 23.00201/v5
Barcode Scanner Model	Scanner_1
Scanner Connection Mode ¹	HID Keyboard
Start and End Date/Time of Testing (UTC)	<Enter Start and End Date/Time>
Client Location ID	68213424-4811-4624-9d20-51545368e2cb
Client ID	21f38a06-3516-4709-8727-4b7ce3996ff3
Client Equipment ID	Equipment Id 1
National System API Version	3.1

Table 1: IT Supplier Information

IT Supplier Qualification – Test Data and Test Book

Test data associated with each test case is based upon functional scenarios, these scenarios are explained at the start of each test case and test step.

The scenario and the action that shall be provided within the test step.




The test data of a medicinal pack (product, batch, serial number and expiry date) also encoded within the 2D data matrix barcode.

The "Initial Public Pack State" reports the state of the test medicinal pack within the NMVS, at the time of the generation of the test-book.

There are several steps throughout the test book that will generate alerts (notification of potentially falsified medicine), uniquely identified by an Alert ID (a.k.a. UPRC, Unique Pack Return Code). These test steps have an "image" icon to indicate that an alert is expected, and that the testing manager will be required to take a screenshot of their software, that will have to be included as part of the testing evidence. These screenshots will be assessed by the NMVO to verify that the information is clearly reported to the end-user.

Ensure the following evidence is clearly presented or attached to your completed test book for each test step that generates an alert ID:

- Alert ID
- Result Code
- Operation Code
- Warning

3.2 Test Case ID: 02_BULK_SUPPLY: NMVS/E2E/Bulk Pack/Supply	
The IT Supplier software that supports bulk operations must be able to perform a bulk supply transaction of multiple packs in various different conditions.	
Test Case Applicability (Yes/No)	
Date and Time of Test Case Completion (UTC)	
Comments	
Test Step	Expected Result
1. Prerequisite: Supply an Active pack via a single pack operation, in order to perform a double supply of the same pack in the next step as part of a bulk supply operation. Attempt to SUPPLY the following pack in a single pack operation:	
Product Code GTIN: 05430002045948 Serial Number: 10FXuHl3dHDNPMqIGt6w Batch ID: xx_124_BS_1_1 Expiry Date: 290314 Initial Public Pack State: Active	 <pre>200 OK { "operationCode": "11210200", "state": "Supplied", "information": "The pack has been supplied.", "productName": "SolidsoftTestBookProduct" }</pre>
Test Step Result:	Comments:
2. Supply four packs with a bulk supply operation Attempt to SUPPLY the following 4 packs in a bulk operation:	
Product Code GTIN: 05430002045948 Serial Number: 12UjzbzrtVNqE7j1hPSv Batch ID: xx_124_BS_2_1 Expiry Date: 290314 Initial Public Pack State: Active	 <pre>(Response varies dependant on configured double dispense limit of market) 200 OK { "operationCode": "12200000", "packs": [{ "pack": { "productCodeScheme": "GTIN", "productCode": "05430002045948", "serialNumber": "12UjzbzrtVNqE7j1hPSv", "batchid": "xx_124_BS_2_1", "expiryDate": "290314" } }], "result": { "operationCode": "11210200", "state": "Supplied", "information": "The pack has been supplied.", "productName": "SolidsoftTestBookProduct" } } OR { "pack": { "productCodeScheme": "GTIN", "productCode": "05430002045948", "serialNumber": "10FXuHl3dHDNPMqIGt6w", "batchid": "xx_124_BS_1_1", "expiryDate": "290314" } }, "result": { "operationCode": "11220201", (Limit ≥ 3) "state": "Supplied", "information": "The pack was previously supplied at this location.", "productName": "SolidsoftTestBookProduct", "numberOfAttempts": 2 } }</pre>
Add pack to the bulk supply request. This pack was SUPPLIED in pre-requisite step 1.	
Product Code GTIN: 05430002045948 Serial Number: 10FXuHl3dHDNPMqIGt6w Batch ID: xx_124_BS_1_1 Expiry Date: 290314	

Test case applicability and the time of test completion (if applicable) must be provided for each test case.

The expected result of the action performed is provided and must match what the client received. The expected results lines up to the test step data in the left hand column.

The result of the test step must also be completed.

Pass - the response received is the same as the expected result

Fail - the response received differs from the expected result

N/A - the test scenario is not applicable to the IT Suppliers solution (e.g., a pharmacy solution unable to perform wholesaler requests)

The results from certain test cases within the test book vary depending on differences in market configuration such as the double dispense limit and the double dispense time limit. Where this occurs the expected results will inform that there are varied responses and contain each of the possible expected results, separated by 'OR'.

R15: On disconnection of a national system from the European Hub (e.g. UKNI, 1 Jan 2025), if an IMT request is made that could only be fulfilled by the disconnected system, the NMVS will translate the response from the Hub into an A22 error code and message "Market not available" and an appropriate audit event generated. The Verification API will present a HTTP response of 503 and operation code of B1020001. Future planned enhancement of EMVS will allow the Hub to generate A22 codes directly

IT Supplier Qualification – Test Evidence

Test evidence can be submitted through the NMVS Administration Portal upon submitting the test book for review.

The testing period should be specified, along with any other necessary testing evidence.

NOTE: the testing period timestamps have to be specified in the UTC time-zone, and NOT in the local time-zone. If the correct time frame is not provided, the logs automatically extracted by the NMVS will not contain all the necessary information for the NMVO to assess the testing activity performed.

Files may be attached by using the 'Add Files' button, and there is an option to categorise file types and provide a description.

Please note that the permissible file types are limited to jpg, pdf, docx, png, csv, xlsx, log and txt. When a test book is under review further test evidence cannot be submitted via the NMVS Administration Portal.

Where a test case generates an alert and causes the Client System Graphical User Interface (GUI) to display a warning, it is necessary to take a screenshot of the warning and record it.

The IT supplier is required to return the generated Qualification Test Book, with all necessary information filled in (IT Supplier Information, Test Case Applicability, and Test Step Results). The IT supplier is also required to submit transaction logs of all transactions performed as part of the testing with the completed test book (in either an Excel or CSV file format).

Please note that sections of the test book that are deemed incomplete, and missing required evidence, will require resubmission and will cause delay in qualification. On the other hand, excessive supplementary evidence should be avoided.

2.5 IT Supplier Information	
IT Supplier Name	Example Wholesaler
IT Supplier Test Manager Contact Email	example@example.com
IT Supplier Test Manager Contact Name	Example Manager
Environment Tested Against	xx IQE
Client System Build/Version Number	FMD Solution 23.00201/v5
Barcode Scanner Model	Scanner_1
Scanner Connection Mode ¹	HID Keyboard
Start and End Date/Time of Testing (UTC)	12/03/2024 10:00:00 – 12:00:00
Client Location ID	68213424-4811-4624-9d20-51545368e2cb
Client ID	21f38a06-3516-4709-8727-4b7ce3996ff3
Client Equipment ID	Equipment Id 1
National System API Version	3.1

Table 1: IT Supplier Information

Submit Test Book ✕

* Start Date of Testing (UTC)


* End Date of Testing (UTC)

Please choose the time period during which the testing was conducted and upload the completed test book, accompanied by any supporting evidence.

Add Files

File Name	Categories	Description	Uploaded By	File Size	Actions
NMVS Qualification Test Book Data v2.4_50.xlsx	Test Book x x v		pharmacysuperuser@exa...	0.04 MB	x
20240122-095716.jpg	Screenshot x x v		pharmacysuperuser@exa...	4.87 MB	x
NMVS Qualification Test Book v3.0_34.docx	Test Book x x v		pharmacysuperuser@exa...	0.60 MB	x

Submit
Close

3.9 Test Case ID: 09_ALERTS: NMVS/E2E/Single Pack/Alerts	
The IT Supplier software must be able to provide sufficient information to the end-user for alerts raised by the system in various conditions.	
Test Case Applicability (Yes/No)	Yes
Date and Time of Test Case Completion (UTC)	12/03/24 - 11:32:00
Comments	
Test Step	Expected Result
1. Attempt to supply a pack already decommissioned as Stolen by another location Attempt to SUPPLY the following pack:	409 Conflict
Product Code GTIN: 05430002045948 Serial Number: 11j9PHFYCKpPJJqwekw Batch ID: xx_124_Alerts_1_1 Expiry Date: 290314 Initial Public Pack State: Stolen	 <pre> "operationCode": "51220300", "alertid": "calertid", "state": "Stolen", "warning": "The pack cannot be supplied because it is already decommissioned as stolen at another location. An alert has been raised.", "productName": "SolidsoftTestBookProduct", "amsLink": "camsLink", "alertCode": "A24" </pre>
Test Step Result: Pass	Comments: Received expected result. Alert screenshot evidence XX-9IU-KFG-JCD-LKA-654.png
2. Attempt to reactivate a pack that has a barcode with an error on the printed Batch Expiry Date	

IT Supplier Qualification – Action Submit Testbook

Submit Test Book

* Start Date of Testing (UTC)
Start Date of Testing (UTC) must be more than 07/03/2024 16:53:37.

* End Date of Testing (UTC)
End Date of Testing (UTC) must be less than 07/03/2024 16:56:54.

Please choose the time period during which the testing was conducted and upload the completed test book, accompanied by any supporting evidence.

Add Files

File Name
NMVS Qualification Test Book v3.0_34.docx
NMVS Qualification Test Book Data v2.4_50.xlsx

Submit Test Book

* Start Date of Testing (UTC)
* End Date of Testing (UTC)

Please choose the time period during which the testing was conducted and upload the completed test book, accompanied by any supporting evidence.

Add Files

File Name	Categories	Description	Uploaded By	File Size	Actions
	All ▾				
NMVS Qualification Test Book v3.0_34.docx	Test Book x ▾		nmvs.ssr+wholesaler@gmail.com	0.60 MB	🗑️
Screenshot (493).png	Screenshot x ▾		nmvs.ssr+wholesaler@gmail.com	0.21 MB	🗑️

Please ensure all files have a category selected.

Submit **Close**

Validation: Start Date and End Date of testing are mandatory fields, and must fall within valid datetime range. Start Date must be after the Testbook was created. End Date cannot be in the future. Note: The Start Date and time as well as the End Date and time must be greater than the Testbook creation date timestamp.

Text describing the file added can be entered here. This field is optional, can be blank.

Test evidence files (pdf, xlsx, jpg, docx, log, txt) can be added using the 'Add Files' button

Individual test evidence files can be removed by clicking the delete icon

Validation: All evidence files uploaded must be given a category: Test Book, Screenshot, Log or Other.

Submit button becomes enabled when there are changes. Click it to submit Testbook to system, user is returned to main panel.

IT Supplier Qualification – Next steps

After the IT supplier submits the test book for revision, the NMVO is notified via email and can proceed with the assessment of the testing activity, using the set of test evidence provided by the IT supplier and the logs automatically extracted by the NMVS.

If the NMVO is not fully satisfied with the provided evidence, they can reopen the test book, which will allow the IT supplier to perform further testing and/or provide more evidence, and finally resubmit again the test book for review.

Once the NMVO is satisfied with the overall qualification activity, they will mark the test book as Certified, which will deem the qualification activity as successfully completed.

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1.1	01-May-2024	Quality Review	Matt Stellmacher
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Document Classification

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Complete Revision History

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Name	Title/Responsibility	Company
All	All staff	Solidsoft Reply NMVO Group
All	All staff and contractors	Solidsoft Reply
All	All	Solidsoft Reply NMVS System Users










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