# NMVS Self Service Qualification Testbook Guide for IT Suppliers

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Audience: IT Suppliers for Pharmacies, Wholesalers, Hospitals



Revision History

\* <u>Complete Revision History</u> can be found within the appendix.



### Document Approval

Name	Role/ Title	Signature	Date	Meaning of Signature
Nicholas Houghton	Author	Signature is documented in the PDF sign-off sheet for this presentation.		I am signing to certify this document has been produced following the prescribed process and that it meets technical requirements.
Steven Sloggett	Development Lead	Signature is documented in the PDF sign-off sheet for this presentation.		I am approving this document to clarify that it meets technical requirements.
Rizwan Rehman	Project Manager	Signature is documented in the PDF sign-off sheet for this presentation.		I am approving this document to certify that it meets business requirements.
Matt Stellmacher	Senior CSV Consultant	Signature is documented in the PDF sign-off sheet for this presentation.		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 <u>endpoints page</u> 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.

IT Sup	plier Qualifi	cation														
C	ireate															
ID	IT Supplier	API Version	Client Syste	Barcode Sc	Client Locat	Location Na	Client Id	Equipment Id	IT Supplier	IT Supplier	Te	Created Da	Ce Start Date o	End Date of	Test Book S	Actio
		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 - Portal**

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



## 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 version of their client software in the 'User-Agent' header. 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.
- Client Location ID\* used by the system to extract transaction logs for the testing activity.
- Client ID\* used by the system to extract transaction logs for the testing activity.
- Client Equipment ID\* used by the system to extract transaction logs for the testing activity.
- 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.

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.

* IT Supplier Name	Example Wholesaler			
* IT Supplier Test Manager Contact Email	example@example.com			
* IT Supplier Test Manager Contact Name	Example Manager			
* Client System Build/Version Number	FMD Solution 23.00201/v5			
* Barcode Scanner Model	Scanner_1			
* Scanner Connection Mode	HID Keyboard			
* Client Location Id	68213424-4811-4624-9d20-51545368e2cb	Test Location 1		
* Client Id	21f38a06-3516-4709-8727-4b7ce3996ff3	Equipment ld 1		
	24			

T 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 <sup>1</sup>	HID Keyboard	
Start and End Date/Time of Testing (UTC)	<enter and="" date="" end="" start="" time=""></enter>	
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	



### IT Supplier Qualification – Test Data and Test Book





## 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.

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.

	S	ubmit Test Book			×
* Start Date of Testing (UTC)	14/03/2024 18:00:00				
* End Date of Testing (UTC)	14/03/2024 18:03:17				
Please choose the time period during which the tes	ting was conducted and upload the com	pleted test book, accompanied by any supporting evid	ence.		
Add Files					
File Name	Categories	Description	Uploaded By	File Size	Actions
	All •				
NMVS Qualification Test Book Data v2.4_50.xlsx	Test Book × × ×		pharmacysuperuser@exa	0.04 MB	
20240122-095716.jpg	Screenshot × $\times$ ×		pharmacysuperuser@exa	4.87 MB	Î
NMVS Qualification Test Book v3.0_34.docx	Test Book × × v		pharmacysuperuser@exa	0.60 MB	<b>T</b>
	Subn	Close			

T 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 <sup>1</sup>	HID Keyboard	
Start and End Date/Time of Testing (UTC)	<u>12/03/2024 10:00:00 – 12:00:00</u>	
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	

#### 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)	<u>12/03/24 - 11:32:00</u>			
Comments				
Test Step	Expected Result			
<ol> <li>Attempt to supply a pack already decommissioned a Attempt to SUPPLY the following pack:</li> </ol>	s Stolen by another location			
Product Code GTIN: 05430002045948 Serial Number: 111pHR/CkptUjqwekw Batch ID: x, 124, Alerts _1 Expiry Date: 290314 Initial Public Pack State: Stolen	499 Conflict "operationCode"; "51220300", "state"; "Stote", "state"; "Stote", "state"; "Stote", "state"; "Stote", "state"; "Stote", "state"; "Stote", "state"; "Stote", "state"; "Stote", "state"; "Stote", "state: "stote", "stote: "stote", "stote: "stote", "stote: "stote:			
Test Step Result: Pass Comme	ents: Received expected result. Alert screenshot evidence XX-9IU-KFG-JCD-LKA-654.png			
2. Attempt to reactivate a pack that has a barcode with	n an error on the printed Batch Expiry Date			



### IT Supplier Qualification – Action Submit Testbook

	Submit	Test Book		×	<u>.</u>		
* Start Date of Testing (UTC)	07/03/2024 16:30:00 Start Date of Testing (UTC) must be more than 07/0	03/2024 16:53:37.	Validation: Start Date and End Da mandatory fields, and must fall w	ate of testing a re vithin valid datetime range.			
* End Date of Testing (UTC)	07/03/2024 18:30:00 End Date of Testing (UTC) must be less than 07/03/	/2024 16:56:54.	Start Date must be after the Test Date cannot be in the future. <mark>Note: The Start Date and time as</mark>	book was created. End well as the End Date and			
Please choose the time period during which the test	ting was conducted and upload the completed test b	ook, accompanied by any supporting evic	time must be greater than the Te timestamp. Subme reserved	stbook creation date		×	
File Name	* Start Date of Testing (UTC)	07/03/2024 16:53:38					
NMVS Qualification Test Book v3.0_34.docx	* End Date of Testing (UTC)	07/03/2024 16:56:54		Text desi entered	cribing the file here. This fiel	e added can be d is optional, can be	7
NMVS Qualification Test Book Data v2.4.50 xlsx	Please choose the time period during which the te	esting was conducted and upload the con	npleted test book, accompanied by any supporti	ing evidence. blank.			_
rest evidence files (pdf, xlsx, jpg, docx,	File Name	Categories	Description	Uploaded By	File Size	Actions	
og, txt) can be added using the 'Add iles' button	NMVS Qualification Test Book v3.0_34.docx	Test Book × × ×		nmvs.ssr+wholesaler@gmail.com	0.60 MB	;←	Individual test evidence files can be removed by clicking the delete icon
	Screenshot (493).png	Screenshot × X ×		nmvs.ssr+wholesaler@gmail.com	0.21 MB		
Please ensure all files have a category selected.		Test Book Log					
		Other					
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			Close				
main panel.							SOLIDSOFT

### Document Review History

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Document Classification

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### Distribution List

Name	Title/Responsibility	Company
All	All staff	Solidsoft Reply NMVO Group
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