Národní organizace
pro ověřování
pravosti léčiv

CZECH MEDICINE VERIFICATION SYSTEM

CERTIFICATION OF SW SUPPLIER

FOR CZMVS R19

October 21, 2026

SOFTWARE SUPPLIER CERTIFICATION

Introduction

This document describes the application software certification process for suppliers of FMD solutions for pharmacies and distributors.

In particular, the document contains detailed instructions for using the "Test-book" – a tool in the CZMVS environment for "self-certification" of FMD application software.

Note: Some examples used in the document may contain data specific to the end user type (distributor or pharmacy), but all processes and functions are equally applicable to both types of organizations.

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Terminology

National Organisation for the Verification of Medicinal Products (CZMVO/NOOL)
An organisation established by national stakeholders for the purpose of administrating the national system and verifying medicinal products for the Czech Republic.

National System for Verification of Medicines (NMVS)
A system within the European verification of medicines that serves as a verification platform for the Czech Republic. Local organisations verify the authenticity of the product by connecting to this system.

Local organisations
Organisations that are required to use CZMVS to verify the authenticity of the product (pharmacies or distributors).

Users

- A system user is a physical user, i.e. a person.
- Users communicate with CZMVS via the CZMVS management portal (or the EVA emergency verification portal).
- Users need an CZMVS account to log in to the management portal.
- Users for ISW suppliers will be set up with the appropriate user role with all the necessary permissions ("Qualification testing/control") to perform their role.

SOFTWARE SUPPLIER CERTIFICATION PROCEDURE

MAIN STEPS:

1. Sign a Non-Disclosure Agreement (NDA) with Solidsoft Reply (which provides IT solutions for CZMVS). You can download the NDA from the CZMVO website (https://www.czmvo.cz/en/system-users/it-software-providers-registration-process).
   Send a scan of the signed NDA to **Solidsoft Reply support for the Czech Republic**: czmvo.support@reply.com, **with a copy to CZMVO**, (it@czmvo.cz).
   Solidsoft will then give you access to the support portal (NMVS Developer Portal), which contains technical specifications, codes, and other information needed to program new functionalities for your information system. One account is always created for each company. In the NMVS Developer Portal, you will have access to a **test integration environment (CZMVS - ITE)** where you can test the required new functionalities (especially communication).
   Please contact Solidsoft Reply support (in English) with any technical questions. Technical support - online support (**12 x 6**). https://solidsoft.freshservice.com/support/home.

2. When you have modified your system, **request access to the qualification environment (CZMVS - IQE) from CZMVO** (it@czmvo.cz). In this environment, you will generate a **Test Book** and perform a certification test to verify the suitability of your solution for deployment within the FMD. Once you consider the test complete, send information about the completion of the self-certification to CZMVO.

3. **CZMVO** will receive the documentation from your testing, verify it, and, if accepted, issue a **Certificate**. After successful certification, the supplier may connect their system to the **National Medicines Verification System (NMVS)**.
   Your software solution for the **FMD project** can then be offered to your clients in the Czech market.

NOTE FOR RECERTIFICATION:

If the FMD software supplier is already certified, **verify** before starting the recertification process that the option ***"IT Supplier Qualification"*** is available in IQE. If this option is not visible in the main side menu of CZMVS, **contact CZMVO** IT team **to have it activated**.

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SW SUPPLIER CERTIFICATION – ENVIRONMENT

The Test-book will be generated for a specific market in the NMVS Integrated Quality Environment (IQE). The Test-Book can only be used for the intended market in which the related data was generated. The API endpoints of the intended market where the Test Book was generated can be found in section 2.1 of the Test Book and on the endpoints page of the **ITE** Developer Portal.

The Test Book for SW supplier qualification can be generated in self-service mode on the IQE NMVS Administration Qualification Test Book page. Links to the NMVS Administration Portal can be found on the Endpoints page, which is referenced by the link mentioned above.

2. Qualification Test Guidance

2.1 Environment

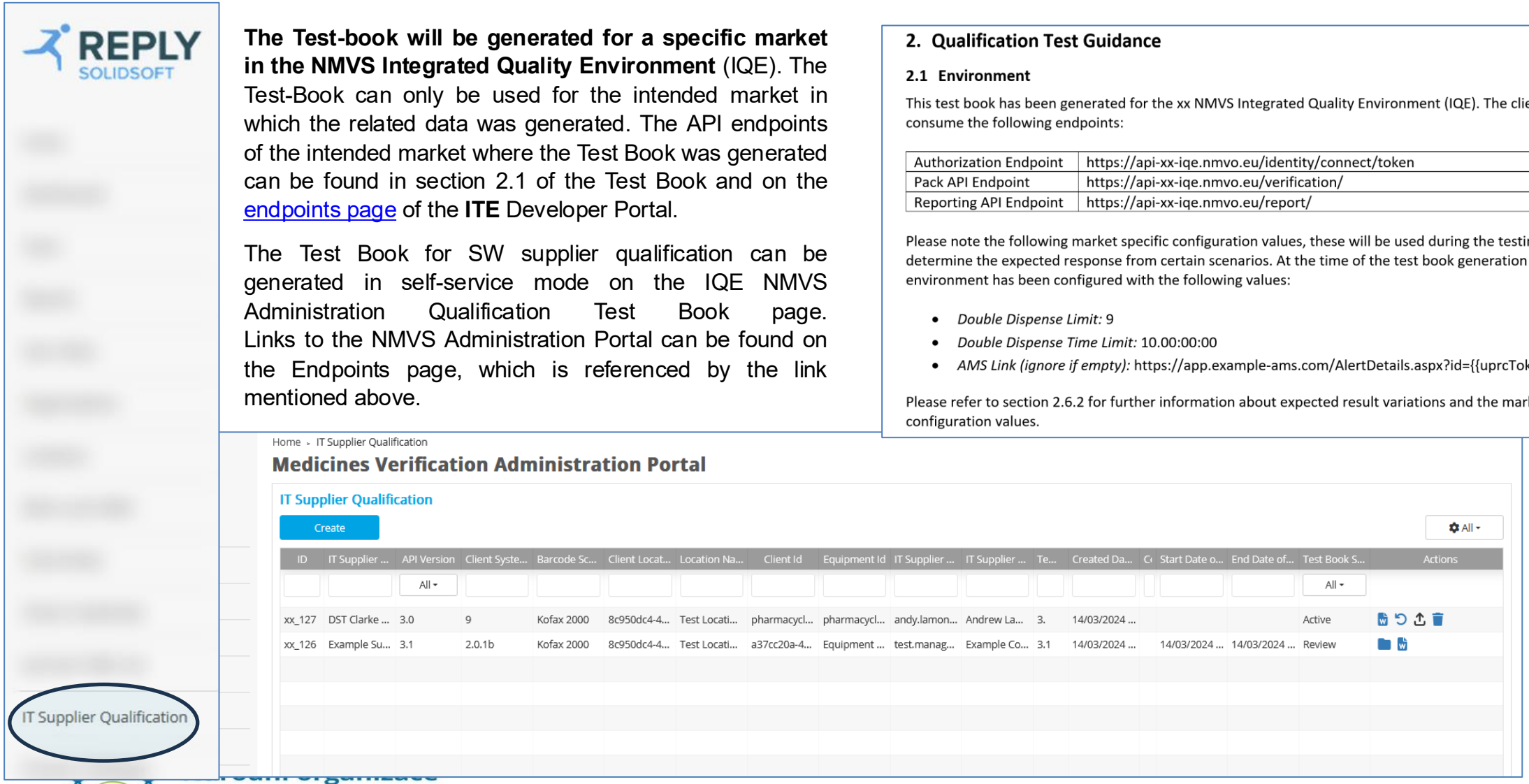
This test book has been generated for the xx NMVS Integrated Quality Environment (IQE). The client solution must consume the following endpoints:

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.



pro ověřování pravosti léčiv

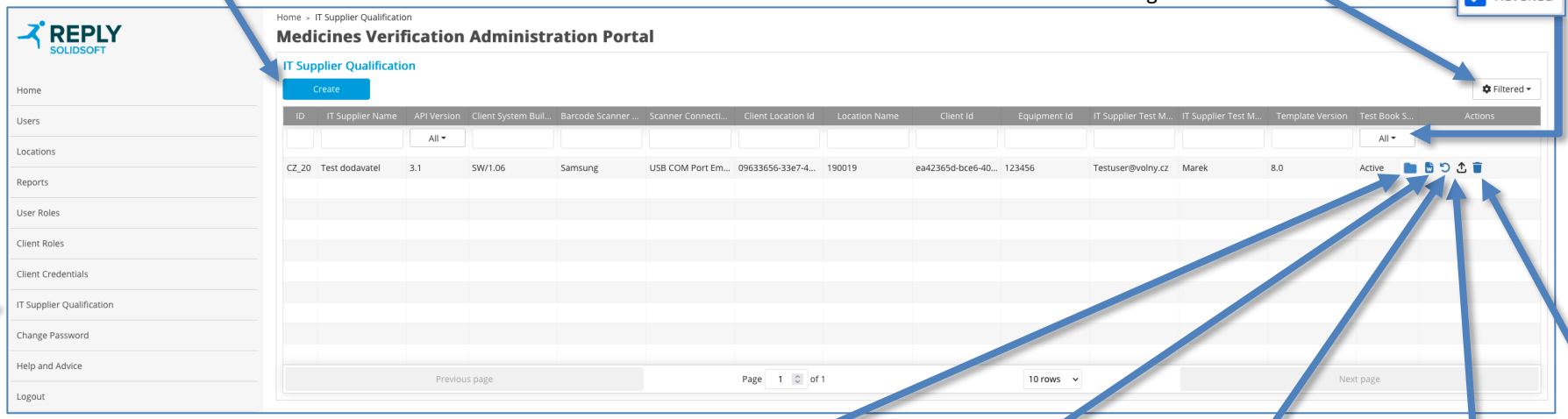
IT SUPPLIER QUALIFICATION

Warning: The *Supplier Software Qualification* function is available only in the IQE environment.

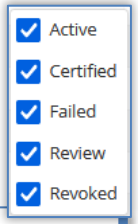
The page will appear in the menu list if CZMVO has made it available for the given organization.

Click the ‚Create' button to create a new Test-Book.

Columns can be shown / hidden using column selector



Test Book status can be one of:



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 CZMVO has reviewed and certified the outcome of the Test Book.

Failed - testing has been completed and the CZMVO has reviewed and considered the outcome and deemed the testing to have failed.

Review – the CZMVO is reviewing the test evidence after submittal by the SW Supplier.

Revoked – when a previously certified Test Book has its certification revoked.

The IT Supplier Qualification page will display the following columns:

- Qualification Test Book 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

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 SW supplier to delete a Test Book. This option is available on Active, Failed and Revoked Test Books.

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SW SUPPLIER QUALIFICATION - CREATE TEST BOOK

- **IT Supplier Name*** - Name of the SW vendor conducting the testing

- **IT Supplier Test Manager Contact Email*** - Contact e-mail address of the manager conducting the testing.

- **IT Supplier Test Manager Contact Name*** - Contact name of the manager conducting the testing.

- **Client System Build/Version*** - **Supplier Software Name and Version** – the name and version of the supplier's software / the version tested. The same information should be used in the HTTP "User-Agent" header. This is used to identify transactions with CZMVS and to verify that the software being used has been certified.

- **Barcode Scanner Model*** - Manufacturer and model of the barcode used for testing.

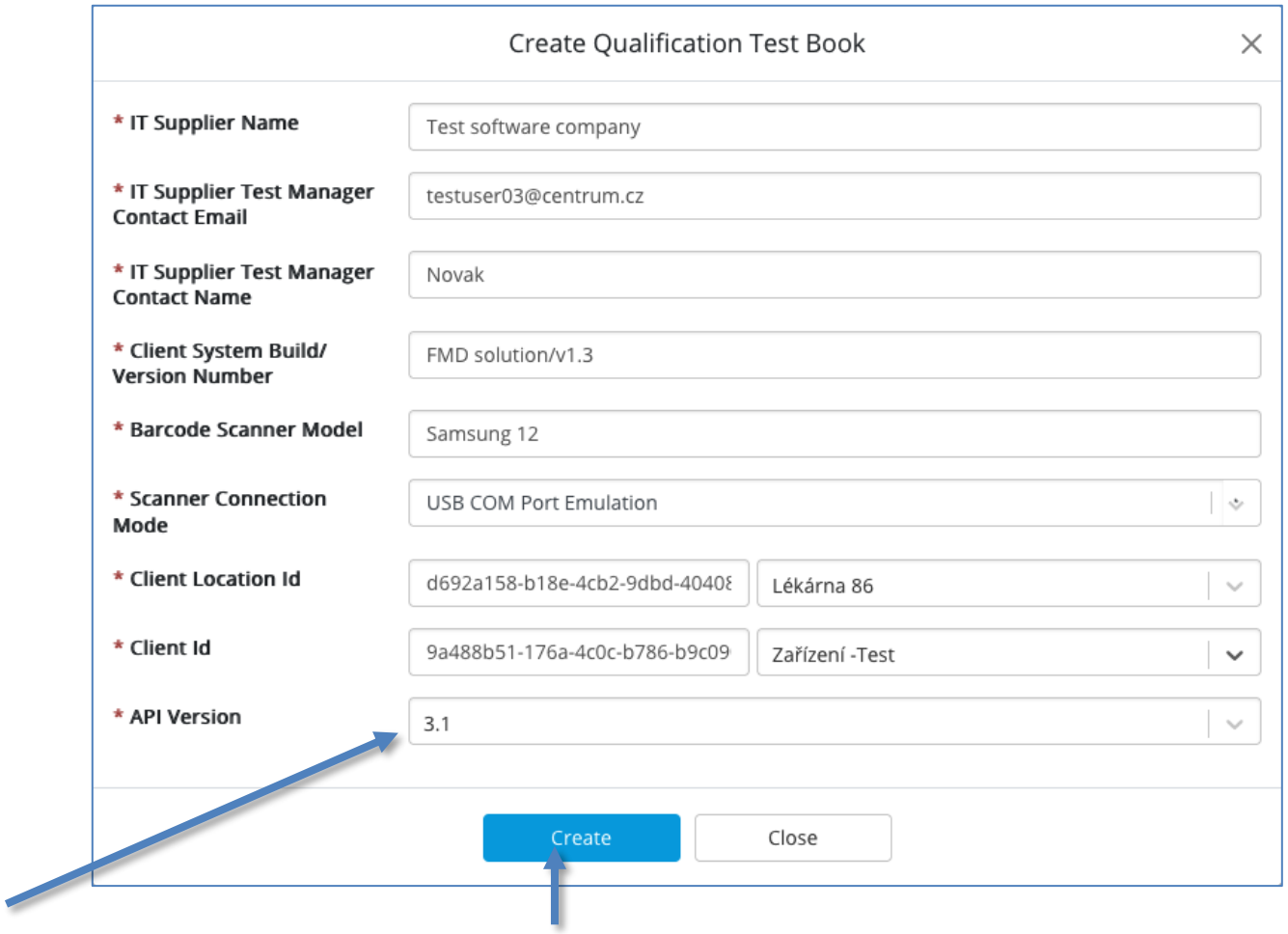
- **Scanner Connection Mode*** - he method by which the scanner connects to the computer. For example: Bluetooth (BT), USB, HID keyboard, serial port, etc.

- **Client Location Id*** - Unique identifier of the test location. List of facilities (test pharmacy, test warehouse) that were previously configured in the 'Locations' tab.

- **Client ID *** - Client device assigned to the selected branch; this parameter is required to connect to CZMVS.

- **API Version*** - The API version used for integration with the national system, specified by the HTTP header emvs-api-version in requests (e.g., 3.1). It is set based on the API version requested/supported in the Test Book.

Note: When preparing for certification, choose only a version that is supported or higher. The selected version will appear in the generated Test Book.



Click the ‚Create' button will create a Test Book.

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IT SUPPLIER QUALIFICATION- CREATE TEST BOOK

After creating the Test Book, **the 'Start and End Time of Testing'** is automatically populated, i.e., the time when the testing was conducted.

This will be used to obtain transaction logs of the executed tests.

This information will be updated by the IT supplier and provided as part of the test evidence for review within the Test Book.

It is necessary to follow the time format : **DD/MM/YYYY HH:MM – HH-MM**

(example: 12/03/2024 10:00 – 12:00).

Note: When submitting the Test-book, the time data (start and end of the test) must be entered in the **UTC time zone**, not in the local time zone (CET) (i.e., CET-1 or CET-2 for daylight saving time).

If the correct time frame is not provided, the logs automatically extracted by the CZMVS will not contain all the necessary information for the CZMVO to assess the testing activity performed.

2.5 IT Supplier Information

IT Supplier Name	Test software company
IT Supplier Test Manager Contact Email	testuser03@centrum.cz
IT Supplier Test Manager Contact Name	Novak
Environment Tested Against	CZ IQE
Client System Build/Version Number	FMD solution/v1.3
Barcode Scanner Model	Samsung 12
Scanner Connection Mode[1]	USB COM Port Emulation
Start and End Date/Time of Testing (UTC)	12/03/2024 10:00:00 – 12:00:00
Organisation Type	Wholesaler
Client Location ID	d692a158-b18e-4cb2-9dbd-404089bb055d
Client ID	9a488b51-176a-4c0c-b786-b9c090748d86
Client Equipment ID	Zařízení -Test
National System API Version	3.1

Table 1: IT Supplier Information

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IT SUPPLIER QUALIFICATION - TESTS

Test data for individual tests are based on functional production scenarios. At the beginning of each test scenario, they are also explained.

The scenario and the actions that will be performed within each test.

Data of the tested medicinal product packaging (Product code, Batch ID, Serial Number, Expiry date) encoded in a 2D Matrix code.
During testing, there are several steps that generate so-called "Alerts" (notifications of a potentially counterfeit medicinal product), uniquely identified by an Alert ID (also referred to as UPRC, Unique Pack Return Code).

These test scenarios are marked with an **icon**, indicating that an Alert is expected, and that the tester will need to capture a screenshot of the software, which will be included in the test documentation.

Ensure that for each individual test generating an Alert (Alert ID), the details for recording in your Test Book are clearly stated or attached, including:

- 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)	Yes
Date and Time of Test Case Completion (UTC)	12/03/24 - 11:32:00
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: 10FXuhI3dHDNPMqiGt6w
Batch ID: xx_124_BS_1_1
Expiry Date: 290314
Initial Public Pack State: Active
		200 OK
		{
		"operationCode": "11210200",
		"state": "Supplied",
		"information": "The pack has been supplied.",
		"productName": "SolidsoftTestBookProduct"
		}

Test Step Result Pass		Comments: Received expected result. Alert screenshot evidence XX-9IU-KFG-JCD-LKA-654.png
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: 12UjbzhrtVNqe7j1hPSv
Batch ID: xx_124_BS_2_1
Expiry Date: 290314
Initial Public Pack State: Active
		(Response varies dependant on configured double dispense limit of market)
		200 OK
		{
		"operationCode": 12200000,
		"packs": [
		{
		"pack": {
		"productCodeScheme": "GTIN",
		"productCode": "05430002045948",
		"serialNumber": "12UjbzhrtVNqe7j1hPSv",
		"batchId": "xx_124_BS_2_1",
		"expiryDate": "290314"
		},
		"result": {
		"operationCode": "11210200",
		"state": "Supplied",
		"information": "The pack has been supplied.",
		"productName": "SolidsoftTestBookProduct"
		}
		},
		{
		"pack": {
		"productCodeScheme": "GTIN",
		"productCode": "05430002045948",
		"serialNumber": "10FXuhI3dHDNPMqiGt6w",
		"batchId": "xx_124_BS_1_1",
		"expiryDate": "290314"
		},
		"result": {
		"operationCode": "11220200", **(Limit ≥ 3)**
		"state": "Supplied",
		"warning": "The pack was previously supplied at this location.",
		"productName": "SolidsoftTestBookProduct",
		"numberOfAttempts": 2
		OR
		"operationCode": "11220201", **(Limit = 2)**

Add pack to the bulk supply request. This pack was SUPPLIED in pre-requisite step 1. **Product Code GTIN:** 05430002045948 **Serial Number:** 10FXuhI3dHDNPMqiGt6w **Batch ID:** xx_124_BS_1_1 **Expiry Date:** 290314 (- only if market setting for double dispense limit[1] ≤ 1 or double dispense time limit[2] is exceeded)		

For each test scenario, it must be indicated (**YES/NO**) whether it was executed. If the scenario was executed, the test completion time must be provided in the following format: **DD/MM/YYYY HH:MM:SS** (e.g., 12/03/24 11:32:00).

The expected outcome of the performed action is provided here and must match what the client received. Rows with expected results continue up to the test step details in the left column.

The test result in „comment" field must also be filled in.

Pass – the received response matches the expected result.

Fail – the received response differs from the expected result.

N/A – the test scenario is not applicable/implemented for the IT solution by the vendor (e.g., a solution for pharmacies that is unable to fulfil wholesalers' requirements).

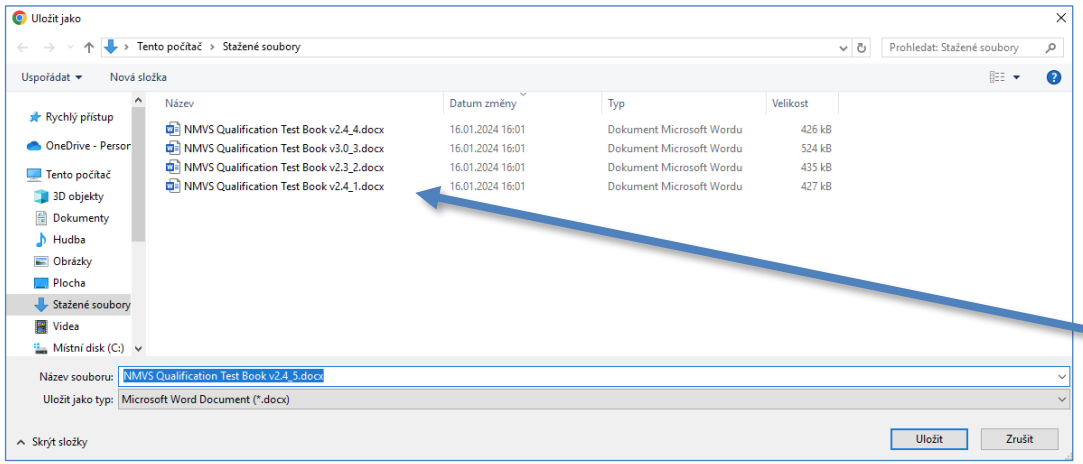
The results of some test scenarios within Test-Book may vary depending on differences in configurations for individual markets, for example, in the time limits for duplicate issuance.

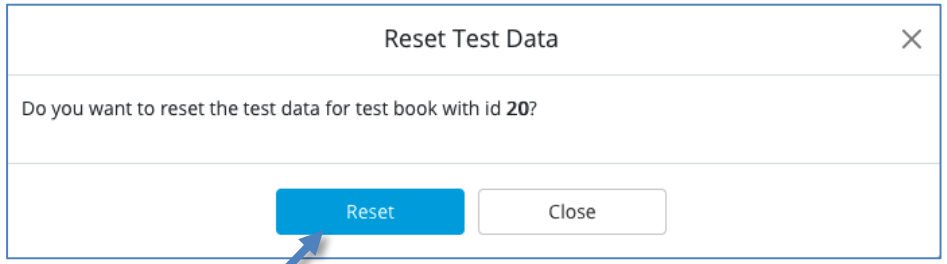
In cases where such differences occur, the expected results will indicate the existence of multiple possible responses and list all possible expected outcomes separated by the term "OR."

If a test scenario generates an Alert and causes the client system's graphical user interface (GUI) to display a warning, a screenshot of the warning must be taken and documented.

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SW SUPPLIER QUALIFICATION - ACTION



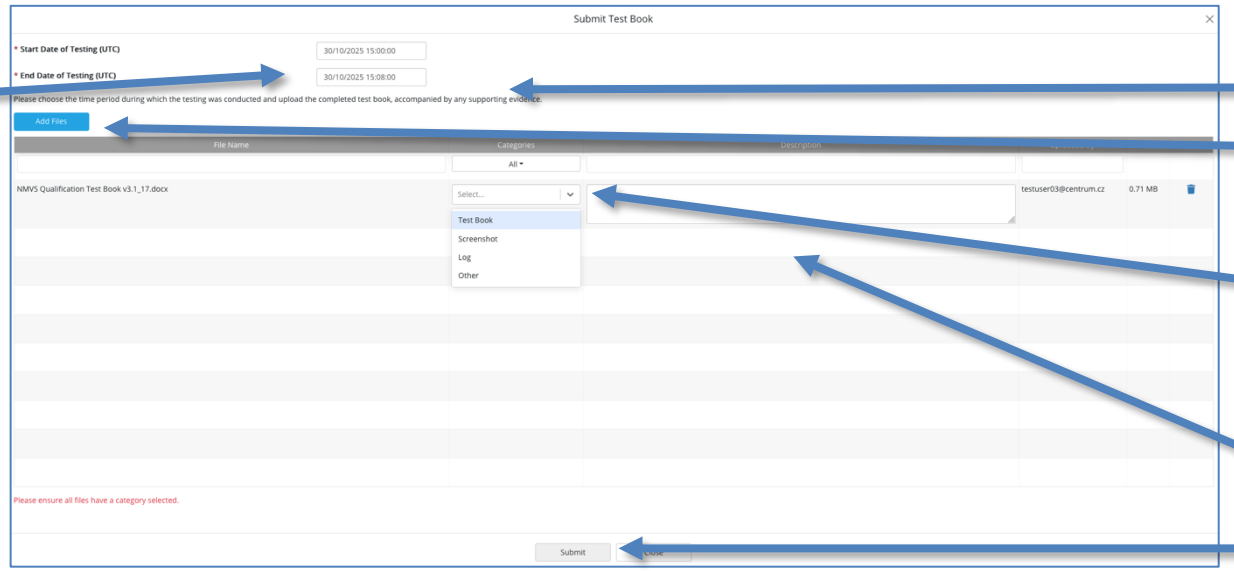


Clicking this icon will open a dialog box where you can confirm the reset of test data for the selected Test Book.

Clicking this icon will save the Test Book in Word format to local storage.

The start and end dates of testing are mandatory fields and must fall within a valid time range according to the tests performed. The start date must be after the creation date of the Test Book. The end date must not be in the future.

Warning: The test start and end dates must be entered in the UTC time zone, **not in the local time** zone.
If the correct time frame is not selected, automatically extracted records from CZMVS will not contain all the necessary information required by CZMVO to assess the performed testing activity.



By clicking the icon , the dialog box will require the time interval during which the testing was conducted.

Use the “Add File” button to upload the completed Test Book in Word format. The following formats are supported for other files: **jpg, pdf, log, txt, docx, png, csv, xlsx.**

Files can be attached using the “*Add Files*” button, after which you can select their category and provide a description.

Here you can enter text describing the added file. This field is optional and can be left blank.

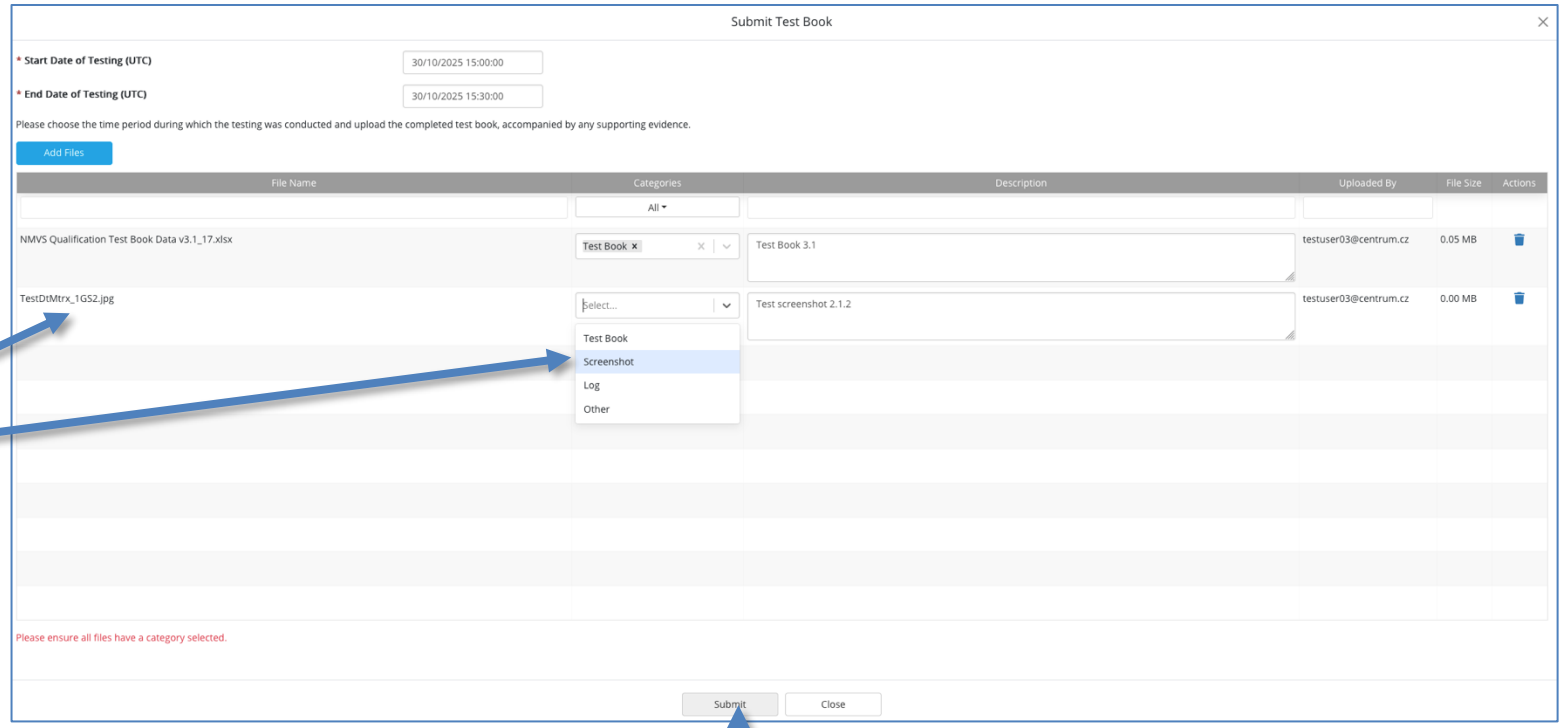
Once the Test Book has been submitted using the “*Submit*” button, only the “*Download*” action will be available in the main menu.

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SW SUPPLIER QUALIFICATION – APPENDICES

WARNING
Beyond the mandatory attachments containing application screenshots, marked in the Test Book with the image symbol , CZMVO requires at least **two additional screenshots** of the user interface for record-keeping purposes. These screenshots must clearly display the informational message, the operation code, and guidance for the user on the next steps.

You may name these files according to the IDs of the corresponding test scenarios to make their identification during evaluation easier.



After submitting the Test Book, the testing materials will be forwarded to CZMVO, where they will review and assess them. You will be informed of the results.

Národní organizace pro ověřování pravosti léčiv

FINISHED SUPPLIER SOFTWARE CERTIFICATION

After the SW Supplier submits the Test Book for review, CZMVO is notified by e-mail and may proceed to assess the testing activities using the test evidence files provided by the SW Supplier and the logs automatically generated by the CZMVS system.

If CZMVO is not fully satisfied with the provided evidence, they may reopen the Test Book, allowing the SW supplier to perform additional testing and/or provide further evidence, and ultimately resubmit the Test Book for review.

Once CZMVO agrees with the overall qualification activities, they will mark the Test Book as certified, thereby considering the qualification process successfully completed.

Subsequently, CZMVO issues a Certification (Acceptance Protocol) and sends it to the company's contact e-mail specified in the Test Book.

Note: The Certificate (Acceptance Protocol) is currently issued for a **period of three years**. However, this period may be shortened or extended depending on changes in CZMVS.