Guide to Certification of FMD software

Effective from 08 January 2024

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1. INTRODUCTION

The following information describes the FMD (Falsified Medicines Directive) software certification process for an FMD software provider to the Irish market. Certification is the process by which you, the FMD software provider, demonstrate that your software has been successfully tested against a set of test cases, that it meets all of IMVO's certification requirements, and is ready to connect (or may remain connected) to the Irish Medicines Verification System (IMVS).

2. ONBOARDING OF FMD SOFTWARE PROVIDER

You must first register with IMVO before beginning the certification process:

2.1 When you contact IMVO to request connection to the IMVS, you are asked to complete an IMVO New FMD Software Provider form to provide details about your organisation and your FMD software solution.

2.2 IMVO then completes a legitimacy check of your company by checking your website and other relevant sources to view existing company products and services. You must operate in the software or pharmaceutical industries and be able to show you have a valid reason to develop software to facilitate connection of end-user(s) to the IMVS.

Once the two steps above are complete, Solidsoft Reply gives you access to the software development kit (SDK) and also to the IMVS integrated test environment (ITE) to test the connection between your solution and the IMVS.

3. CERTIFICATION OF FMD SOFTWARE

FMD software must be certified before it can connect to the production IMVS. The following requirements must be met to achieve certification of FMD software with IMVO:

3.1 Successful baseline testing in the IMVS quality testing environment (IQE);

3.2 Implementation of IMVO's additional functional requirements; and

3.3 Provision of your training video/recording.

Detailed information on each of these requirements is below.

4. BASELINE TESTING IN IQE

Baseline testing involves the execution of a set of test cases contained in a Qualification Test Book. Successful execution of these test cases is the first requirement for connection to the IMVS. Prior to initiating this step, you should have successfully performed informal testing against the IMVS Integrated Test Environment (ITE). Please refer to the developer portal, https://developer-ite.nmvo.eu/it-supplier-testing/it-supplier-qualification-testing-guidance, for detailed technical information from Solidsoft Reply on ITE and IQE testing.

The steps in the baseline testing process are as follows:

4.1 When you have completed testing in the ITE environment and are ready to begin the certification process in the Integrated Quality Environment (IQE), please send an email to info@imvo.ie requesting to begin the certification process.

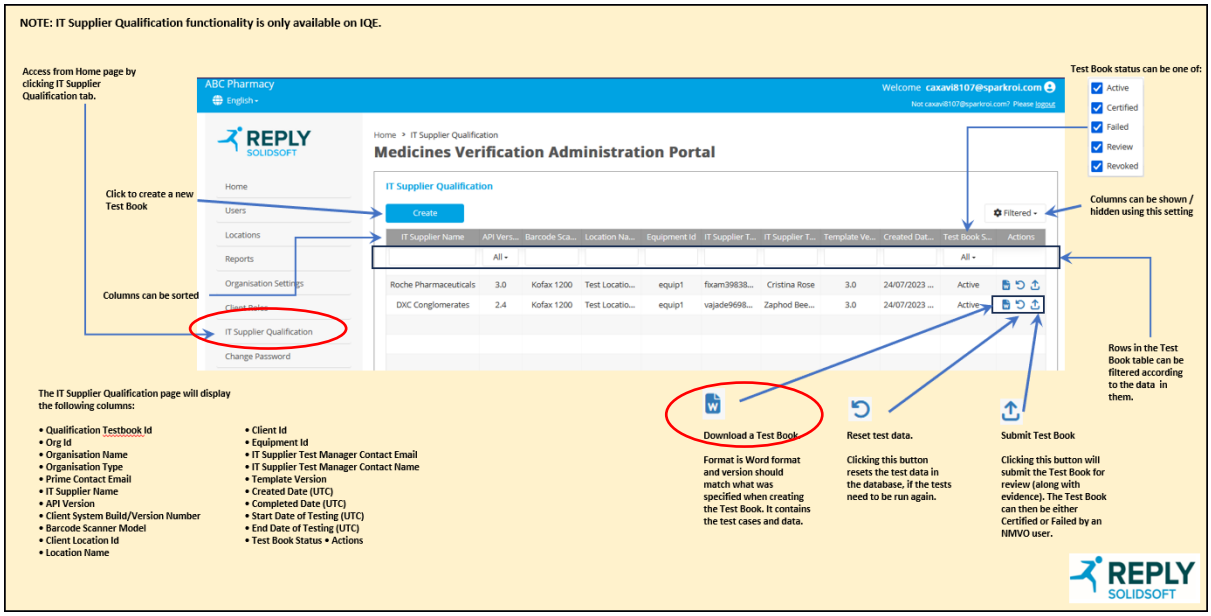
4.2 If this is your first time testing your FMD software in the IQE environment, IMVO will assist you in setting up your own test Organisation and Location in the IQE IMVS.

4.3 If you already have a test Organisation and test Location in IQE, IMVO will check that the required setting is in place to enable you to generate your own Qualification testbook (note a change implemented in Release 13 enables FMD software providers to generate testbooks, reset test data and submit completed testbooks directly in the IMVS IQE Portal).

4.4 Connect your FMD software to the IMVS IQE endpoints for Ireland as published on the developer portal ***https://developer-ite.nmvo.eu/apis/endpoints*** and testing can now begin. The following should be noted:

- There is no time limit to complete the testing.
- If required, you may reset the test data back to the original state to restart the test process.
- You cannot submit test evidence for tests performed prior to a test data reset.
- If you reset the test data, you must re-do any tests you have already performed unless IMVO has already reviewed the test results and evidence for those tests and confirms that you do not have to re-do them.
- You are required to know which test cases are applicable to your customer (i.e. pharmacy/hospital or wholesaler). If a test case is not applicable, it must be clearly marked as not applicable.
- Screenshots of the software's Client GUI showing the result of the test cases must be included with the testing documentation. The screenshot should show the pack information (product code, batch number and serial number), the colour-coded response and the link to IMVO's online help page if an alert was raised.

4.5 Download a new testbook in the IQE IMVS Portal, on the IT Supplier Qualification page as shown in the screenshot below:



4.6 Following successful execution of all applicable test cases, please submit the completed Qualification Test Book in the IQE IMVS Portal and also email all the documented test results to info@imvo.ie. The application for certification will be rejected if clear screenshots and test evidence are not provided.

4.7 You must provide a written explanation if there are reasons for not executing any of the test cases.

4.8 Once you submit your completed Qualification Test Book this sends an automatic notification to Solidsoft Reply who will then provide IMVO with a copy of their transaction logs.

4.9 IMVO will then review the test results and evidence and compare them to the Solidsoft transaction logs.

5. IMVO SPECIFIC REQUIREMENTS

5.1 **RAG (red, amber, green) colour coding -** Colour-coded responses, also known as traffic light colours, must be provided by the FMD software. The colour coding is determined by the operation code returned in the IMVS response. IMVO defines the appropriate colour to map to each operation code returned by the IMVS and you must implement these exact mappings. The mappings can be found here.

5.2 **URL links to IMVO online help pages** - Links to IMVO's online help pages must also be implemented. Similar to the colour coding, it is the operation code that determines the appropriate online help page. IMVO defines these mappings. and they can be found here.

5.3 **Manual entry -** Expiry date entry must not be an option on the screen for manual entry of pack data. It is not a legal requirement for this information to be entered in order for the pack to be authenticated[1] and IMVO's experience has shown that when end-users attempt to verify or decommission packs manually, they frequently enter the expiry date in the wrong date format, thereby causing an alert (expiry date mismatch).

5.4 **User Agent Header -** The correct software name and version must be provided in the User Agent header. If you supply different FMD software applications (e.g. a web-browser based application and a client-based application) or have different build/versions of your software, the User Agent Header must clearly identify the software name and version.

5.5 **Provision of recording of baseline testing or training video** - It is beneficial for the IMVO team to have a good understanding of how each FMD software works when speaking to end-users (pharmacies, hospitals and wholesalers) about FMD scanning and alert management. Therefore please provide IMVO with either a recording of the full baseline testing performed (which clearly shows the software's front-end screens) or alternatively an end-user training video or other training materials.

6. COMPLIANCE DECLARATION

Once IMVO has reviewed the results of the tests and confirmed that all applicable tests have been executed successfully and certification requirements met, you will be asked to complete a Compliance Declaration form to confirm in writing the name and version of the FMD software application used to perform the testing. This form is also used to capture all the functionality (including any added value functionality) provided by the FMD software being certified.

[1] Commission Delegated Regulation on Safety Features (EU) 2016/161, Article 11

7. TECHNICAL CONNECTION CERTIFICATION REPORT

When the signed Compliance Declaration form has been received by IMVO, the Technical Connection Certification report for this FMD software will be issued by IMVO and your FMD software may then connect to the IMVS.

8. TESTING TIMESCALES

Please allow a minimum of 10 working days for your test results to be reviewed and the Technical Connection Certification Report to be issued.

Note: any new end-user of the IMVS (pharmacy, wholesaler or hospital) intending to use this FMD software will not be issued with client credentials and cannot connect to the IMVS until the FMD software is certified. It is the responsibility of the FMD software provider to ensure sufficient time is allowed to achieve certification prior to the end-user needing to connect to the production IMVS.

9. IMVO WEBSITE

IMVO maintains details of all certified FMD software on its website. IMVO will use information provided about your FMD software (including added value functionality) on the Compliance Declaration to update the FMD Software Providers section of the IMVO website.

10. RE-CERTIFICATION

When the IMVS API version that the FMD software was certified against is no longer supported, you must re-certify your software when upgrading to a supported version. FMD software must also be recertified when upgrading to a major release, from example, upgrading from API 2.4 to API 3.0.

The process for re-certification of software is the same as for certification except you may re-use your existing test Organisation and Location in IQE - new ones are not required. The onboarding process (Section 2. above) is not repeated for re-certifications.

11. WITHDRAWAL OF CERTIFICATION

IMVO reserves the right to withdraw certification if the certified FMD software version is found to be not functioning properly after deployment and/or you do not respond to requests to fix known issues within a reasonable timeframe.

Also note that IMVO has the right to disconnect individual end-users or restrict their access to the IMVS if their FMD software endangers the security or functioning of the IMVS or the EMVS (in whole or in part).