

Frequently Asked Questions

Serialisation, medicine coding, NMVS operations, wholesaler onboarding and baseline testing

This collection brings together the questions most frequently received by NMVO Italia on serialisation, medicine coding, NMVS operations, wholesaler onboarding and the baseline testing of software suppliers.

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A. Product coding: GTIN, AIC, Product Master Data and free samples

A1 We produce different packs for the retail channel and the hospital channel, under the same AIC. Can we assign two different GTINs?

Yes, that is correct. If the packs are different from the start (for example because the security paper device is cancelled only for the hospital channel), it is correct to use two different GTINs.

The NMVS has no problem managing several GTINs under the same AIC, as long as they are all uploaded to the EU Hub. The rule is that **one GTIN cannot identify two different items**.

A2 We produce a single batch for the retail channel, and only later some packs are “de-stickered” (the pharmaceutical stamp is cancelled) so they can be sent to the hospital channel. Is it correct to use a single GTIN? What if in the future we produce batches intended directly for the hospital channel?

In this scenario it is correct to use **a single GTIN**. If in the future the company decides to produce batches intended for the hospital channel, it will be correct to assign a dedicated GTIN.

A3 For a medicine distributed in both the public and the private channel, is it better to have one GTIN for each AIC or a different GTIN for each channel? Are both options supported?

From a technical point of view, **both options are possible**. The regulations state that the product code (GTIN) is assigned by the manufacturer, so the choice mainly depends on the company's needs.

- **One GTIN per AIC:** this is the most common standard for physically identical products.
- **A different GTIN per channel:** this gives more detailed data (for example for samples, which have the same AIC but a smaller pack size).

A4 How should free samples with a reduced content be managed in the Product Master Data? Pack size is a mandatory field and, since it refers to the AIC, there would be an inconsistency between the physical content and the declared content.

Free samples must carry the same safety features as the product for sale, with decommissioning before distribution to doctors.

For samples with a reduced content, it is possible to **assign a dedicated GTIN** to the sample pack and enter it as a separate product in the Product Master Data in the system. In this way the inconsistency between the physical content of the pack and the declared data disappears.

It has been confirmed with GS1 that two different GTINs can be associated with the same AIC code when the packs differ in the quantity of content.

A5 Who is responsible for deactivating the unique identifier of medicines supplied as free samples?

The obligation lies with the **Marketing Authorisation Holder (AIC holder)**, who must flag the pack as a free sample in the repositories system (by setting the status **FREE SAMPLE**) and ensure it is deactivated before supplying it to the persons authorised to prescribe it, as required by Article 41 of Regulation (EU) 2016/161 for samples supplied under Article 96 of Directive 2001/83/EC.

A6 Can the depositary deactivate free samples on behalf of the AIC holder?

Yes, the depositary can carry out the operation on behalf of the AIC holder if this is expressly provided for in a written contract. However, the AIC holder remains the **only party legally responsible** for this activity.

A7 Can the Product Code (PC) shown on the packs of medicines entering Italy be the GTIN?

Yes. The Product Code (PC) corresponds to the GTIN, a 14-digit numeric code assigned by the manufacturer according to GS1 standards.

On the pack, the HRI (Human Readable Interpretation) must show the abbreviation “PC” followed by the GTIN code.

A8 For Italy, is it possible to use an NTIN that includes the AIC number, so that the AIC does not have to be shown as the fifth HRI (as happens, for example, in Spain)?

No. The coding requirements for Italy have been included in the latest revision of the EMVO guide (EMVS Master Data Guide v.10.0 of 15 October 2025).

As required by Legislative Decree 10/2025, for Italy you must upload the **GTIN as Product Code** and the **AIC (in the 8+1 format) as the mandatory National Code**. Under the Regulation, this means the AIC must also be shown in human-readable format (HRI) on the pack.

A9 Some AIC codes have a “/E” or “/M” suffix (e.g. 046918049/E, 035728017/M). Should they be included in the Product Master Data and in the Data Matrix?

No. The AIC code is a 9-digit number: any “/E” or “/M” suffixes must be excluded from both the Product Master Data and the Data Matrix.

A10 How can the designation of a depositary as a “designated wholesaler” be proven within the NMVS?

The status of designated wholesaler can be proven **only through the written contract** between the depositary and the Marketing Authorisation Holder (AIC holder).

As stated in the EMVS Master Data Guide, the Holder must also provide the list of wholesalers (ID, name and address) when uploading the Product Master Data to the EMVS. The designation is not visible to NMVS users: for this reason, Appendix 5 of the EMVS Master Data Guide recommends showing the AIC holder, the designated wholesaler and the recipient on transport documents (delivery notes and invoices).

B. Data Matrix, HRI and packaging

B1 What is the sequence of the elements to be encoded in the Data Matrix? Does it have to be the same for all production sites? Source: Ministry of Health FAQ

As stated in the FAQ of the National Competent Authorities (Annex 2 of Operating Instructions no. 1 under Article 13, paragraph 4, of Legislative Decree no. 10 of 6 February 2025 Link: <https://www.salute.gov.it/new/sites/default/files/All.%20%20-%20FAQ.pdf>), the sequence of the GS1 Data Matrix code and that of the related HRI must **match exactly**. In addition, in line with GS1 standards, the GTIN must **always come first**. <https://www.salute.gov.it/new/sites/default/files/All.2-FAQ.pdf>

Different sequences (for example GTIN + SN + EXP + LOT + AIC, or GTIN + LOT + EXP + SN + AIC) are therefore valid, even across different production sites, provided that:

- the GTIN stays in the first position;
- the HRI faithfully reflects the Data Matrix.

B2 What should we do if there is not enough space on the carton to show all the HRI and the AIC next to the Data Matrix? Can the HRI be spread over several flaps? Source: Ministry of Health FAQ.

According to the FAQ published on the Ministry of Health website (Annex 2 of Operating Instructions no. 1 under Article 13, paragraph 4, of Legislative Decree no. 10 of 6 February 2025 Link: <https://www.salute.gov.it/new/sites/default/files/All.%20%20-%20FAQ.pdf>), the HRI must be **grouped together in a compact form and stay next to the Data Matrix**. It is therefore not possible to spread PC, SN, LOT and EXP over different flaps. <https://www.salute.gov.it/new/sites/default/files/All.2-FAQ.pdf>

The Decree of 6 March 2025 provides that the HRI should, where possible, be adjacent to the two-dimensional barcode, while the AIC may be non-adjacent to the optical code but must be **as close as possible**. The AIC should therefore preferably be on the same panel or, depending on the size of the carton, on another side as close as possible to the Data Matrix.

For small cartons, we recommend asking AIFA for official feedback.

B3 Can we print the price as a fifth line next to the Data Matrix, to avoid updating the artwork every time the price changes? If the AIC is shown on the flap, can it be the last element in the Data Matrix? Source: Ministry of Health FAQ

As stated in the FAQ published on the Ministry of Health website (Annex 2 of Operating Instructions no. 1 under Article 13, paragraph 4, of Legislative Decree no. 10 of 6 February 2025 Link: <https://www.salute.gov.it/new/sites/default/files/All.%202%20-%20FAQ.pdf>), the price may be printed on the fifth line. **The price is not an HRI element** and therefore must not be included in the GS1 Data Matrix. <https://www.salute.gov.it/new/sites/default/files/All.2-FAQ.pdf>

The HRI sequence must be the same as the one in the Data Matrix: the string encoded in the Data Matrix must therefore follow the order used on the pack, with the AIC as the last element.

For any further doubts, we recommend contacting the National Competent Authorities.

B4 For sub-batches (parallel import), is it possible to add an identifying letter next to the batch number, in plain text only and not in the Data Matrix?

No. The human-readable information (HRI) must be the exact interpretation of what is encoded in the Data Matrix. Adding an identifying letter in plain text only, even if separated from the batch, could be seen as a data mismatch during manual checks, increasing the risk of false alerts of possible falsification.

B5 Can a transparent seal (ATD) be placed over the Data Matrix and the HRI in the case of very small packs?

This is a solution that **requires caution**. A transparent seal placed over the Data Matrix may cause reflections or distortions and affect correct scanning along the supply chain. If the verification of the safety features cannot confirm the authenticity of the medicine because of reading problems, the system raises a potential falsification alert.

We recommend carrying out readability tests with the manufacturer.

B6 What happens to the wording “Confezione dispensata dal SSN” (“Pack dispensed by the SSN”) with the new Security Paper Device (Dispositivo Carta Valori), which replaces the pharmaceutical stamp and cannot be removed? Source: Ministry of Health FAQ

As stated in the FAQ published on the Ministry of Health website (Annex 2 of Operating Instructions no. 1 under Article 13, paragraph 4, of Legislative Decree no. 10 of 6 February 2025 Link: <https://www.salute.gov.it/new/sites/default/files/All.%202%20-%20FAQ.pdf>), once the Security Paper Device “Annex A” is applied to the packs, the wording “Confezione dispensata dall’SSN” (“Pack dispensed by the SSN”) will **no longer be necessary**. <https://www.salute.gov.it/new/sites/default/files/All.2-FAQ.pdf>

B7 What requirements and wording must the packs of medicines intended as free samples have?

According to Delegated Regulation (EU) 2016/161 (and the related clarifications of the European Commission in Q&A 8.5), **free samples must carry the same safety features** as the product intended for sale.

In addition, for medicines placed on the market in Italy (under Article 4, paragraph 3 of Decree 10/2025 on the Security Paper Device), the following wording must be clearly shown on the pack in indelible ink: «**CAMPIONE GRATUITO - VIETATA LA VENDITA**» (“FREE SAMPLE – NOT FOR SALE”)

C. Stabilisation period and regulatory obligations

C1 Can a batch produced and released by the QP without serialisation before 9 February 2027 be marketed after that date?

Yes. Under Article 13 of Legislative Decree 10/2025, during the stabilisation period (from 9 February 2025 to 8 February 2027) batches may be released with the current pharmaceutical stamp, without serialisation safety features.

These batches may remain on the market until their expiry date (even after 9 February 2027), without having to be repackaged or relabelled.

C2 Does serialisation change the data file that is sent every day to the Ministry of Health (NSIS) with the movements of medicines?

Article 2 of the Decree of 16 June 2026 requires manufacturers, depositaries and wholesalers to send the Central Database the movements of medicine packs, including those leaving the distribution channel, in the way described in the technical specification annexed to the decree, with reference to the following information:

- a)** the sender;
- b)** the identification code of the marketing authorisation in Italy, issued by AIFA;
- c)** the corresponding number of packs;
- d)** the recipient of the supply;
- e)** where applicable, the production batch and the expiry date;
- f)** the economic value of supplies directly charged to National Health Service (SSN) facilities.

Manufacturers, depositaries and wholesalers therefore **continue to send the MOV and FAT data**. Sending to the Central Database remains separate from sending to the NMVS: the two flows do not replace each other.

C3 Are medicines not yet authorised and used under compassionate use covered by Regulation (EU) 2016/161?

No. Since these medicines have no AIC, because they are still under study and not authorised for marketing, they are excluded from the safety feature rules of Regulation (EU) 2016/161, as also confirmed by the European Commission's Q&A 1.6.

C4 Will the Italian NAMS (National Alert Management System) be connected to the European Alert Management System from 9 February 2027?

NMVO Italia's goal is to have the **Italian NAMS connected to the European AMS from 9 February 2027**.

D. NMVS operations

D1 Is it possible to decommission (e.g. reason Destroy) packs belonging to an expired batch? Does the system make them inactive automatically?

No, and it is not necessary. The status of a pack belonging to an expired batch is set **automatically by the system to INACTIVE (Reason EXPIRED)**, even if its serial number has never had any transaction (it was "active" at the time of expiry).

No further transactions can be made on these packs (e.g. Destroy, Stolen, Lock): the system replies with the error `NMVS_NC_PCK_30` without generating an alert. Alerts are generated only for packs with the "Checked Out" property.

D2 What happens if I carry out an operation on a pack belonging to a recalled batch (pack status Recalled)?

No further transactions can be made on these packs (e.g. Destroy, Stolen, Lock): the system replies with the error `NMVS_NC_PCK_30` without generating an alert. The same behaviour applies to withdrawn batches (WITHDRAWN).

D3 Does the system accept batch numbers and serial numbers containing special characters? Is it possible to enter "00" as the day of the expiry date?

From a technical point of view, the system allows **special characters** (e.g. dots, hyphens, percent signs) in both the batch number and the serial number, in line with GS1 specifications. However, the European Commission's Q&A (2.23) recommend using capital letters and avoiding special characters, to reduce reading and manual entry errors.

As for an expiry date with **day "00"**, the EU Hub accepts this value and reads it as the last day of the month indicated.

The system is therefore able to handle both cases.

D4 How can I know whether my scanner reads the GS1 Data Matrix correctly?

You need to contact your supplier and check with them. NMVO Italia also provides a dedicated information page with feedback from the main scanner manufacturers: <https://www.nmvoitalia.it/pistole-scanner-data-matrix/>

D5 What happens if a pack intended for another market (e.g. Spain) is scanned?

When the Data Matrix of a pack intended for a foreign market is scanned, the system does not reject the operation but starts an automatic procedure called **Intermarket Transaction (IMT)**.

The verification flow has the following steps:

- 1. Local check:** the local NMVS carries out an initial check in its own database.
- 2. Forwarding to the EU Hub:** as it does not find the serial number data in its own repository, the NMVS forwards the verification request to the EU Hub.
- 3. Identification of the competent country:** the EU Hub identifies the relevant National System (in this case the Spanish one) and forwards the request to it.
- 4. Verification and reply:** the destination NMVS checks in its own repositories whether the unique identifier exists and what its status is (for example “Active”). The result is sent to the EU Hub, which redirects it to the local NMVS to confirm the operation to the user.
- 5. Synchronisation:** finally, the status is updated in the national repositories involved.

In an Intermarket Transaction, the NMVS does not return the product master data; in addition, the reply contains the notification NMVS_NOTIFY_IMT_01.

E. Wholesaler onboarding

E1 What is NMVS onboarding and why do I have to do it?

It is the process that enables you to operate on the Italian National Medicines Verification System as a Wholesaler, with the creation of your user accounts and the check that your systems communicate correctly with the NMVS.

E2 Which documents do I need to provide to get started?

The authorisation documents for the distribution activity (with VAT number, registered office and operating site) and any additional material required in the initial onboarding request. NMVO Italia will check these data and start the onboarding process.

E3 What do I have to do during the initial check (legitimacy check)?

No action is required from you. NMVO Italia carries out the necessary checks on the documents received: if everything matches, the process continues automatically, without any further input from you at this stage.

E4 What are the tests in the IQE environment and why do I have to do them?

IQE is the quality/test environment of the NMVS. Before operating in production, you must check that your interfaces (the NMVS portal and, if you have one, the integrated L4 system) work correctly, using a pool of test serial numbers (Data Matrix) that will be provided to you.

If you declared in the onboarding request form that you have an integrated system, you must also run the tests through that interface. **It is not possible to continue with onboarding without having run the tests on both interfaces** (if you have both).

E5 I have received the Data Matrix codes for the tests in both GUI and L4: what is meant by L4?

L4 means an **external integrated system**, that is, a technical integration system that connects to the NMVS (for example through API), as opposed to the GUI, which is the graphical interface of the NMVS portal.

If in the onboarding request form you answered “**Yes**” to the item “4. Technical Integration – External system present”, you must also run the tests through the specific technical integration system that your company has.

E6 Which operations do I have to test on the serial numbers provided?

The operations to be tested are, in this order:

- 1. Verify;**
- 2. Dispensing** (decommissioning);
- 3. Undo Dispensing**, on the same serial number that was just dispensed;
- 4. Destroy or Stolen**, on a different serial number (an irreversible operation, to be done last).

If you have a connected L4 system, repeat the same sequence on that interface too.

Together with the serial numbers you will receive a table, to be filled in once the tests are done, with the serial numbers actually used. As shown in the table, the first three operations must be run on the same serial number, while the fourth (irreversible) one must be run on a different serial number.

More serial numbers than necessary are provided, in case you have problems with some of them.

E7 By when do I have to complete the tests?

DEADLINE

Within **7 days** of receiving the e-mail with the serial numbers, by confirming that the tests have been carried out and returning the table with the serial numbers actually used.

If the 7 days are exceeded, NMVO Italia cannot guarantee the smooth timing of the onboarding process, which may take longer because the request loses priority and moves to the back of the queue.

E8 What happens after I have sent the confirmation of the tests?

NMVO Italia downloads the report for each serial number used from the system and starts the test validation procedure to check the evidence. If the result is positive, the IQE checklist is finalised and the creation of the user accounts in the Production environment is authorised.

E9 When will my user accounts be created in Production (PRD)?

Only after the positive result of the IQE tests has been confirmed. At that point NMVO Italia asks IPZS to create the Client and the user accounts in the Production environment, with the same data and roles already checked in IQE.

E10 When can I consider the onboarding complete?

After you have received your user accounts in the Production environment, you will be asked to confirm by e-mail that you have received them and have registered correctly. Only at that point is the process formally considered complete.

E11 What is the difference between the IQE test environment and the Production environment (PRD)? Do the IQE user accounts stay active after I receive the PRD ones?

The two environments are **separate and independent, but functionally identical**.

The IQE user accounts stay active, even after you have received the PRD user accounts.

IQE

Test environment

- **Purpose:** designed and built specifically for tests and trials.
- **Test operations:** can be carried out without any problem.
- **User accounts:** stay active even after you receive the PRD ones.

PRD

Real (live) environment

- **Purpose:** real data and operations are handled here.
- **Test operations:** strictly forbidden.
- **User accounts:** received after the IQE tests have been passed.

PROHIBITION

On the PRD environment it is **strictly forbidden** to carry out test operations. Tests must be run in the IQE consolidation environment, which was designed and built for exactly this purpose.

F. User account management

F1 What should I do after receiving the IQE user accounts?

VERY IMPORTANT

Once you have received the IQE user accounts, use the **ADMIN** user to immediately create an additional ADMIN user, to be used also as a back-up for managing the administration of the user accounts. If one ADMIN account is blocked, the other ADMIN unblocks it. Do the same when you receive the Production user accounts: IQE and Production have separate user accounts.

F2 I need to create Regular users for our different warehouses. Who should I send the data to in order to create the user accounts?

You do not need to send any data. Once you have received the login credentials for the IQE environment, the user with the Admin profile, through the Client ID, is fully autonomous in creating all the additional profiles you want, either “Regular” or further “Admin”.

Therefore, for any additional warehouses (for example Cremona and Padua) you can go straight to setting up the user accounts within the same “Wholesaler XXX” organisation, without having to register again from scratch.

F3 What is the difference between the Admin account and the Regular account?

ADMIN Manages the NMVS users and certificates	REGULAR Carries out verification and dispensing operations on the NMVS
• Responsibilities: operational continuity, IT security and management of the organisation's credentials. • Key activities: managing the user life cycle, renewing digital/ API certificates, escalating system issues. • Scope of activities: management of users and certificates; no operations on packs.	• Responsibilities: traceability and safe supply of the medicine to the patient. • Key activities: checking the status, deactivating (Decommissioning) and restoring (Undo) the serial number. • Scope of activities: operations on packs.

F4 How can I install the NMVS certificate on a new PC after changing computer?

You can transfer and install the same certificate on the new PC by **importing the certificate file**. During the installation procedure you will be asked for the passphrase entered when you first downloaded/installed it.

IMPORTANT NOTE

We strongly recommend that you **keep your "passphrase" safe and securely stored**, because you will need it to enable the certificate on any other devices.

G. Baseline testing for software suppliers

G1 What is baseline testing and what does its approval mean?

Baseline testing shows, from a functional point of view, that a software product in a given version exchanges messages correctly with the NMVS. It is carried out by the software supplier on the Sandbox and submitted on the Software Supplier Portal, where NMVO Italia checks it. The mandatory tests are the minimum requirement for connecting to the Italian NMVS.

WHAT APPROVAL MEANS

An approved baseline test is valid **only for that product in that version**. It is not a general certification of the software and **it does not give access to the IQE or Production environments**: each customer must complete their own onboarding with NMVO Italia.

The onboarding form asks customers for the product name and version and for the baseline testing evidence. If a new version changes the connectivity with the NMVS, the baseline testing must be repeated.

The onboarding process is described on this page: <https://www.nmvoitalia.it/onboarding-nmvs-depositari-e-grossisti/>

G2 For which roles is baseline testing carried out?

At the moment NMVO Italia enables system connection only for this role: **Wholesaler**. Pharmacies and healthcare facilities follow different paths.

A baseline test run and submitted for several roles (Wholesaler, Pharmacy, Hospital) is rejected. In this case the procedure must be repeated, selecting only the Wholesaler role.

G3 How does NMVO Italia check a baseline test?

NMVO Italia carries out three checks on the Software Supplier Portal, in the order shown. **A single failed check is enough** to reject the submission and ask for a new run.

1. **Test summary.** For the requested role the result must be “Tests passed: YES” and all mandatory tests must have “Test Passed = YES”. A failed or unrun optional test does not block approval. The “Test Passed” column of each test case is what counts: the overall result may show NO even when the test cases have passed.
2. **Signed protocol.** It must be a PDF, correctly filled in and signed, and consistent with the summary (see G7).
3. **Transaction logs.** They must be present and refer to the same test pack as the summary.

The reason for any rejection is sent in the portal’s automatic e-mail. If there is more than one reason, they are all listed together, so you can fix everything in one go.

G4 Which are the mandatory tests for the Wholesaler role?

For the Wholesaler role there are **26** mandatory tests, and all of them must pass. In negative tests the expected return code is an error code (highlighted rows). Reference: DOC-300007-10 Baseline Testing Protocol.

Test case	Description	Expected result
TC-G110-01	Verify single pack – Active	NMVS_SUCCESS
TC-G115-01	Bulk verify – PK004-PK008 Active	NMVS_SUCCESS
TC-G115-15	Bulk verify not successful – modified product code	NMVS_NC_PC_01
TC-G120-01	Dispense single pack	NMVS_SUCCESS
TC-G121-07	Undo dispense on non-existent pack – modified serial number	NMVS_NC_PC_02
TC-G125-01	Bulk dispense	NMVS_SUCCESS
TC-G125-05	Bulk dispense not successful – pack already Inactive	NMVS_NC_PCK_19
TC-G127-01	Bulk undo dispense	NMVS_SUCCESS
TC-G130-01 · TC-G135-01	Destroy single / bulk	NMVS_SUCCESS
TC-G140-01 · TC-G141-01	Export / undo export single (with G110 before and after)	NMVS_SUCCESS
TC-G145-01 · TC-G147-01	Bulk export / bulk undo export	NMVS_SUCCESS
TC-G150-01 · TC-G155-01 · TC-G157-01	Sample single / bulk / bulk undo	NMVS_SUCCESS
TC-G160-01 · TC-G161-01	Free sample / undo (with G110 before and after)	NMVS_SUCCESS
TC-G165-01 · TC-G167-01	Bulk free sample / bulk undo	NMVS_SUCCESS
TC-G170-01 · TC-G171-01 · TC-G175-01	Lock single / undo (with G110) / bulk	NMVS_SUCCESS
TC-G180-01 · TC-G185-01	Stolen single / bulk	NMVS_SUCCESS

Optional tests (non-blocking): TC-G110-19, TC-G120-12, TC-G120-13, TC-G120-14, TC-G120-15, TC-G120-16, TC-G120-17, TC-G121-11.

G5 I see items in the logs or in the portal that look like errors: should I be worried?

Not necessarily. Here are three common cases:

- **Red return codes in the logs.** In negative tests the error code is the expected result: for example, for TC-G115-15 the correct result is `NMVS_NC_PC_01`. The expected codes are shown in the table in question G4.
- **Placeholder in the summary.** Next to “Last successful test” you may see the text `{{date, intlDate}}`: this is a graphical defect of the portal and does not depend on how the tests were run.
- **Protocol numbering.** In the table of section 7 of DOC-300007-10 the SN column restarts from 18 after 25, so the numbers from 18 to 25 appear twice. In your communications, always quote the Test Case ID and not the SN number.

G6 How should I prepare and run the baseline testing?

- **Instance and role.** Select “Italy” as the NMVS country (if it is not available, register again on the portal for the Italian instance) and select the Wholesaler role only. NMVO Italia sees only the submissions of the Italian instance.
- **Test pack.** Download it from the “Baseline Testing” section. The “Test & Fix” packs are for trials and must not be submitted: only Baseline Testing packs produce the pass/fail result for NMVO. Do not download a Baseline Testing pack just to try things out: from that moment NMVO Italia automatically receives the result of every test.
- **Name in the requests.** The name attribute of the UserSoftware tag must be identical to the name of the downloaded test pack (DOC-304012, section 6.3).
- **Test Documentation.** Use the version that matches the release active in the Sandbox (DOC-304012).
- **User.** Run all the tests with the same user who created the test pack.
- **Updated documents.** Use the current versions of the protocol (DOC-300007) and of the Test Documentation. Evidence from previous years, from another country, or based on a protocol that is no longer valid is not accepted.
- **Upload.** Upload the signed protocol to the portal after the tests have been run. An incomplete submission, or one made on another national instance, is not visible to NMVO Italia.

G7 How should the protocol (DOC-300007-10) be filled in?

- **Format.** The protocol must be uploaded as a **PDF**, not as a Word file.

- **Section 9 – Baseline Testing Protocol Approval.** It must be filled in (name, title, role, date) and signed. Both a scan of a handwritten signature and an electronic signature are accepted.
- **Section 4 – Test Information.** It contains the **name and version of the software tested**, not the name of the test pack, which must instead be entered in section 11.3 “Test Pack used”. Name and version must match what your customers will declare in the onboarding form (section 4, Technical integration). In “Resp. NMVO” enter NMVO Italia.
- **Section 7.** Fill in the table starting from the results of the summary: every PASS in the protocol must match a YES in the summary. Tests that were not run must be declared and explained in the “Comments” column. Tests that are not relevant to the role (for example TC-G195-01 Mixed Bulk, required only for Pharmacy and Hospital) must be marked as not applicable and not as PASS.

A protocol that is not consistent with the summary and logs visible to NMVO Italia, for example with tests declared PASS without evidence, is not reliable evidence and leads to rejection, even when the technical tests went well. If the protocol is in Word or is not signed, you will be asked to upload the signed protocol as a PDF.

G8 One or more mandatory tests have failed: what should I do?

The evaluation tool compares each request **exactly** with the data and the sequence in the Test Documentation: a test can therefore fail because of the data used or the order of the operations, and not because of the software’s functionality.

Read the test case again before running it, check data and steps against DOC-304012 in the version matching the release active in the Sandbox, and repeat the baseline testing with a new test pack downloaded from the “Baseline Testing” section. All the mandatory tests for the Wholesaler role must pass. The tool also stops at the first failed check in each sequence of requests: a failed test does not confirm that the following steps were correct.

Recurring cases:

- **TC-G115-01:** PK004–PK008 must be used (a frequent mistake is using PK003–PK007).
- **TC-G115-15:** the first digit of the product code must be changed. Expected result `NMVS_NC_PC_01`.
- **TC-G121-07:** the serial number of the pack must be changed before the undo. Expected result `NMVS_NC_PC_02`. If the serial number is not changed, the undo succeeds and the test fails.
- **TC-G141-01, TC-G161-01, TC-G171-01:** the G110 must also be run before and after, as required by the test case.
- **TC-G120-15 (optional):** the serial number changes with the release. In CORE-8.00 the description shows SN0XY7188 but the table shows SN0XY7171; in CORE-9.00 it is SN0XY7088.
- **Bulk tests:** the packs must follow the order shown in the test case (Pack1, Pack2, ...).

NMVO Italia cannot change the result of the evaluation tool, even when the test looks functionally correct (for example for serial numbers in a bulk in a different order): the rule is the same for all software suppliers. In these cases the test must be repeated, following the data and order of the test case.

G9 The test summary does not open or the logs do not appear: what should I do?

Without the summary, NMVO Italia cannot verify the execution. The summary is generated from the transaction logs of the test pack: if the logs are not linked to the test pack, the summary does not exist. Check that:

- the name attribute of the UserSoftware tag is identical to the name of the test pack (DOC-304012, section 6.3);
- the test pack was downloaded from the “Baseline Testing” section and not from “Test & Fix”.

Then repeat the baseline testing and also send the log file in its original format to nmvs_account_setup@nmvo-italia.it.

If the error appears again (for example a 400 error when opening the summary), open a ticket at helpdesk@nmvs.eu, which is the channel for Sandbox and portal problems (DOC-304012, section 4). Write the ticket number in the protocol, in the “Incident Number at Arvato” field, and tell NMVO Italia, who will follow the case with Arvato.mailto:helpdesk@nmvs.eu

TO REMEMBER

Approval is given **only on the portal**, where the summary and logs are generated by the system. Documents sent by e-mail cannot replace them.

G10 What happens if the user changes or the certificate expires during the tests?

The test pack and the chain of transactions are linked to the user who runs them. If the test pack was created with one user and the tests were run with another (for example because of an expired certificate or a new username), some tests fail: for example, undos do not work because the user of the undo is not the user of the dispense.

In this case, create a **new test pack** with the active user and run the whole baseline testing again with that user.