FMD Tutorial

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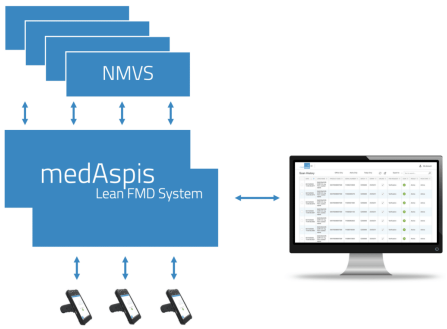
1 The medAspis Lean FMD System

medAspis Lean FMD is an internet-based system that can carry out the legally required checks to prevent medicine counterfeiting in all European countries.

The 2D matrix codes on the medicine packs are usually captured using the medAspis Speed Scanner. This device specialises in the fast capture and processing of 2D matrix codes.

The captured data is transmitted to the medAspis Lean FMD system, stored there, and immediately forwarded to the responsible NMVS (National Medicine Verification System). The pack data is processed there and the result is sent back.

The Lean FMD system stores all this information and immediately displays the result on the medAspis Speed Scanner. If a check result is not positive, the laser scanner is stopped immediately. The operator can check the result straight away; no error goes unnoticed.



1.1 The basic design of the medAspis Lean FMD system

Any number of medAspis Speed Scanners can be connected to the Lean FMD system. Each device always communicates directly with the Lean FMD system. The Lean FMD system is connected to the respective responsible NMVS. Different protocols are supported depending on the NMVS technology used (Arvato, SolidSoft, securPharm).

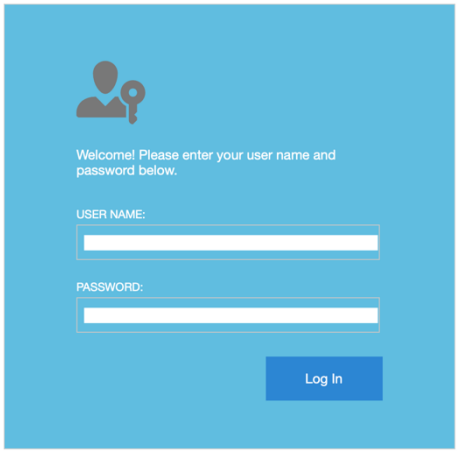
The Control Panel provides a portal for monitoring and controlling the Lean FMD system.

1.2 The system components

The medAspis system uses the mobile medAspis Speed Scanner handheld scanner to scan medicine packs on site. The scan results can be retrieved via the "Control Panel" web portal and processed further there. The system can be booked in different configurations. This tutorial describes the full configuration; optional system components are marked accordingly.

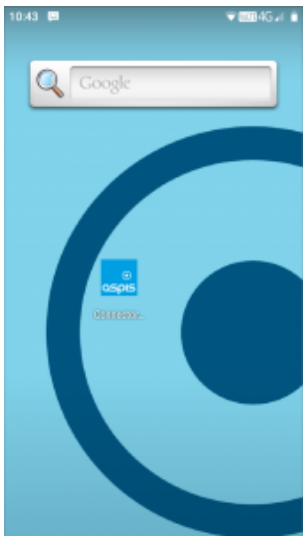
1.3 Getting started with Lean FMD

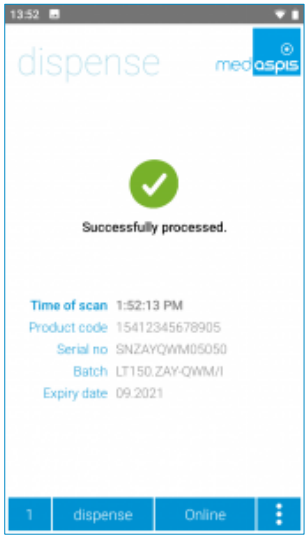
A customer account is provided for every new customer. The medAspis system can be accessed at https://panel.medAspis.org A login field appears, where you log in with your user name (customer account) and a password.



1.3.1 Getting started with the medAspis Speed Scanner

Switch on the medAspis Speed Scanner and open the medAspis Connector⁺ app. Perform a few scans in FMD Verify mode.



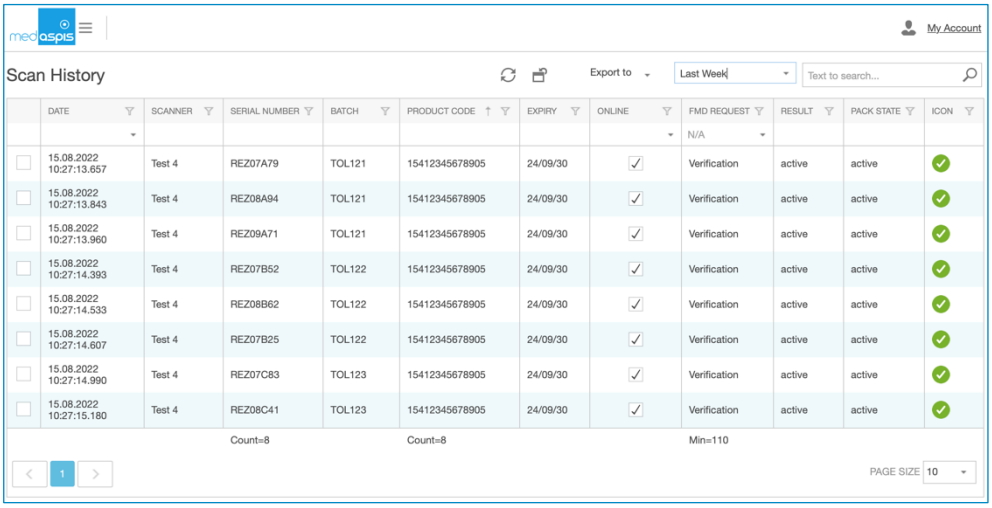


Important: If you receive a warning or an unclear message after the first scan, please stop your first attempt and contact medAspis Support immediately. One of your login details (user ID, password, certificate password) may be incorrect. If you scan more than five times, your NMVS account may be blocked.

If no warnings are displayed, check the Scan History in the Control Panel. After a very short time, you will see the results of your first scans logged here, along with the corresponding responses from the NMVS. You may need to click the Reload button.

1.3.2 Getting started with the Control Panel

Open the Control Panel. The Scan History will open automatically, and you will already be able to see your first scans there.



Congratulations – you are now FMD-compliant!

You will find all further operating instructions and typical use cases further on in this tutorial.

2 The medAspis Speed Scanner

The medAspis Speed Scanner is an Android smart device with a very fast scanner unit. The device can be operated using a pistol grip. The medAspis Connector+ app runs on this device.

The medAspis Speed Scanner is characterised by its fast-scanning speed. Depending on the device type, two different scanning technologies are available. The older models scan all 2D matrix codes that are targeted using the light spot in the centre of the illuminated window. The newer devices feature a matrix scan mode, which captures all 2D matrix codes within the illuminated rectangle simultaneously.

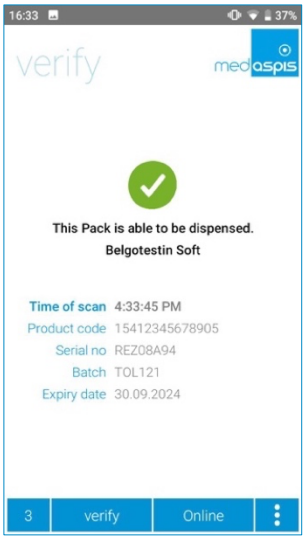


2.1 The user interface of the medAspis Speed Scanner

The graphical user interface is divided into various fixed sections.

The information read from the last scan is displayed centrally, together with a timestamp. Above this, you will find the result of the check carried out by the responsible NMVS. If the system transmits the product name, it is displayed here. This product name may be truncated if the name is too long to fit on one line.

An icon indicates the result: positive (green tick) or negative (red cross). The Solidsoft system displays warnings with a yellow icon. Other warnings – for example, following the scanning of a barcode with an incorrect format – are indicated by a blue icon. A list of all icons can be found in the appendix to this document.



There is a counter in the bottom left-hand corner. This counter counts the number of scanned packs but ignores duplicate scans of the same pack or scans of codes that are not FMD 2D matrix codes. Tapping the number resets it to zero.

To the right of the counter is the FMD menu. This menu allows you to select the FMD operation that will be used to send the 2D matrix codes to the relevant NMVS. The last selected FMD operation remains active until a new operation is selected. For greater clarity, the selected FMD operation is displayed once again in the top-left corner. After accessing the app settings or when an operator logs out, the active FMD operation always resets to 'verify'.

The indicator on the far right shows the current status of the device's internet connection to the medAspis Lean FMD system. The device is usually 'Online'. If the internet connection to the Lean FMD system is disrupted, this is indicated here by the word 'Offline'. In this case, the scanned data is stored on the medAspis Speed Scanner and processed at a later stage. More on this in a separate chapter.

The three dots (⋮) on the far right next to it open the app settings.

2.2 FMD operations

All FMD operations specified by the NMVO can be carried out in the medAspis system. Some of these operations are restricted for use by pharmacies. However, they are still displayed in the FMD menu. If a restricted operation is attempted, an error message will be displayed.

menu option	whole sale	pharmacy
verify	x	x
deactivate	x	x
mark pack as destroyed	x	x
mark pack as exported	x	-
mark pack as sample	x	x
mark pack as free sample	x	-
mark pack as locked	x	-
mark pack as stolen	x	x
reactivate pack	x	x

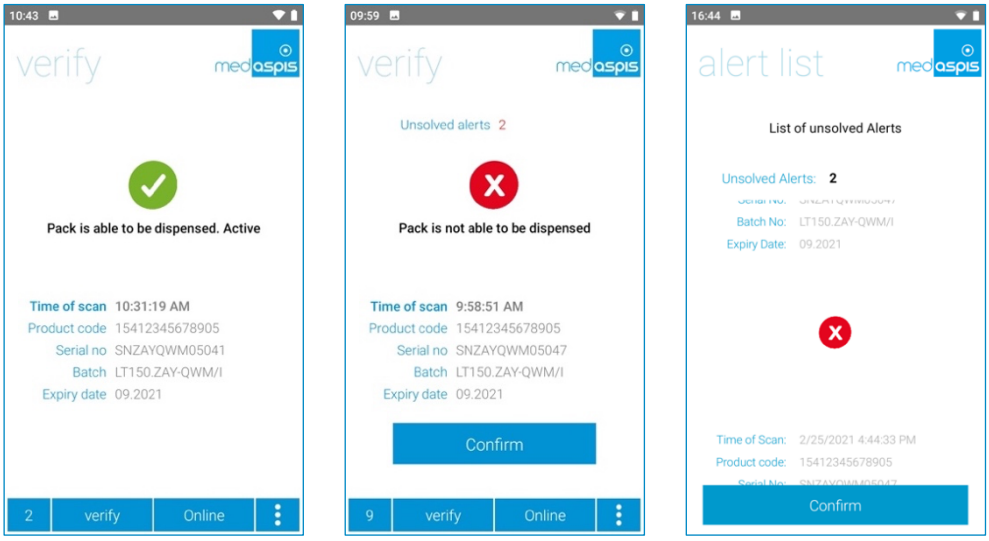
FMD operations can be used to check ('verify') the status of a medicine pack, or to change the FMD status ('dispense'). The deactivation functions 'exported', 'stolen', 'sample', 'free sample', 'locked' and 'destroyed' also change the status of the pack and are used in specific situations. 'dispense' is explained below; the other FMD operations work in a similar way. Most FMD operations can be reversed using 'reactivate' under certain conditions.

2.2.1 Verify

To check the status of a pack, set the FMD mode of the medAspis Speed Scanner to 'verify'. Scan the 2D matrix code on the pack. A 'Verify' command is sent to the relevant NMVS.

Medicine packs can be verified as often as required. A separate line appears in the scan history for each 'Verify' command.

The result of a 'Verify' check may be negative if the medicine pack has already been deactivated.



In this case, the scanner is stopped; you cannot continue scanning but must address the alert. This process is documented by pressing the 'Confirm' button on the medA-spis Speed Scanner's display. This is also recorded in the scan history. In certain cases, confirming the error may disrupt the workflow and can be disabled in the settings.

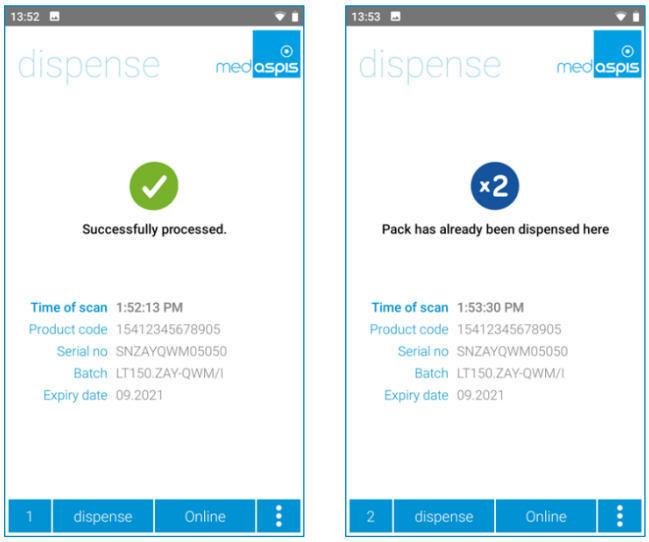
In addition, the affected packs are saved in the medAspis Speed Scanner. The packs can be checked in the alert list. Once the errors have been acknowledged, the 'unsolved alert' counter is reset to zero.

2.2.2 Deactivate

The FMD mode of the medAspis Speed Scanner is set to 'dispense'. The 2D matrix code on a pack is scanned. A deactivation command is sent to the relevant NMVS.

The result can be positive or negative, just as with "verify" and all other FMD operations. The "dispense" command changes the pack's status from "active" to "inactive". A pack that has been set to "inactive" cannot be dispensed again.

A separate line appears in the scan history for each deactivation command.



Deactivating a pack that is already inactive will result in an NMVS error. This error may occur more frequently if a pack is deactivated several times due to carelessness.

The medAspis system is able to recognise a deactivation as a duplicate and does not send it to the NMVS again. Instead, the result of the previous deactivation is displayed once more, but with the 'Double Dispense' symbol . The same entry is also displayed in the Scan History, again with the 'Double Dispense' symbol.

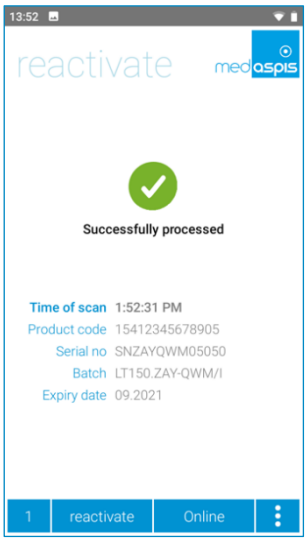
For a duplicate to be recognised, the same pack must have been deactivated within the last 10 minutes using the same FMD command. When Alert Guard is enabled, this period is extended to 2 hours.

2.2.3 Reactivate

Reactivation resets a pack's status from 'inactive' to 'active'. To carry out this function, the FMD menu on the medAspis Speed Scanner is set to 'reactivate'. The 2D matrix code of a pack is scanned, and a reactivation command is sent to the relevant NMVS. It is not necessary to specify the original FMD operation that is now to be reset. This attribute, which is required by the NMVS, is automatically appended to the reactivation command by the medAspis system.

The reactivation function is subject to certain restrictions. For example, a pack can only be reactivated if you yourself (using your own NMVS customer account) deactivated the pack within the last 10 days. Excluded from this are the FMD operations 'marked as stolen' and 'marked as destroyed'. These cannot be reactivated under any circumstances.

The reactivation is displayed as a separate line in the Scan History.

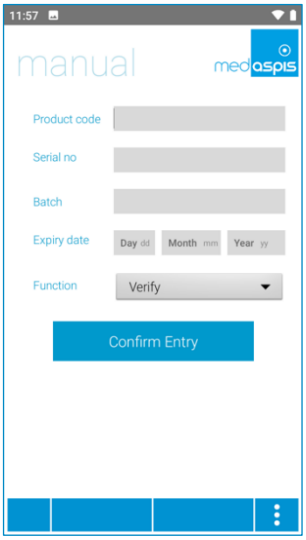


2.2.4 Manual entry

If a 2D matrix code cannot be read by the scanner, the data can be entered manually. To do this, the required fields must be completed and the desired FMD operation specified. If an expiry date consists only of the year and month, the day field in the display is either left blank or filled with 0 (zero).

The NMVS response reappears on the main screen of the medAspis Speed Scanner.

In the scan history, the manually entered data is not specifically highlighted. The FMD command resulting from the manual entry is displayed in exactly the same way as if it had been generated by the scanner.



2.3 The functions of the medAspis Speed Scanner

2.3.1 FMD scanning with the medAspis Speed Scanner

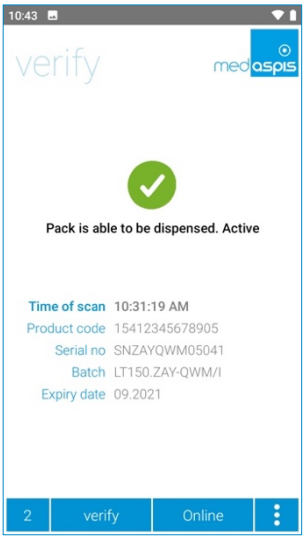
First, select the required FMD operation from the FMD menu on the medAspis Speed Scanner. If no selection is made, the default operation is 'verify'.

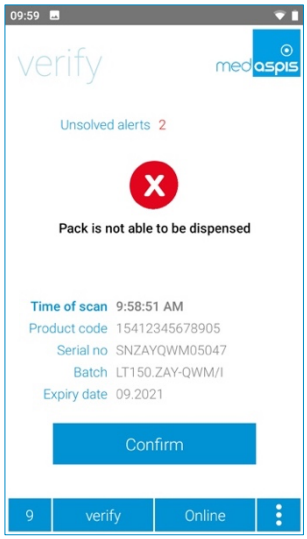


When the laser scanner is activated, 2D matrix codes can be captured and then transmitted to the NMVS using the selected FMD operation. The data processed by the NMVS is formatted and displayed on the screen.

If the result is positive, the next code is scanned automatically. If the result is negative, the laser scanner stops automatically and the operator must acknowledge the alarm displayed on the medAspis Speed Scanner screen. If the code read does not match the expected syntax in GS1 encoding or PPN encoding (available only in Germany), the scanning process is aborted and the message 'No FMD' is displayed.

Both the data set read from the 2D matrix code (product code, serial number, expiry date, batch number) and the data set returned by the NMVS are stored in full within the data structure of the Lean FMD system. The result is analysed and interpreted. The corresponding result is displayed on the medAspis Speed Scanner's screen and saved in the scan history.

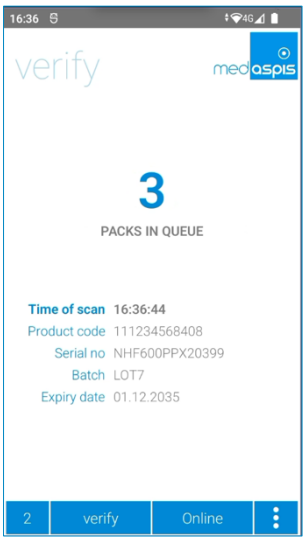




The data can be further processed in the Control Panel. The most important function is the display of scan data. This data can be filtered and exported in almost any way.

2.3.2 The Scan Accelerator

Under certain circumstances, the medAspis Speed Scanner may be able to scan faster than the NMVS can process the codes. As the NMVS can only process all requests strictly sequentially, one after the other, the data from the scanning process is initially placed in a queue, from where it is then fed to the NMVS for processing. This procedure ensures that the operator can scan as quickly as they wish and that all packs are reliably processed by the NMVS.



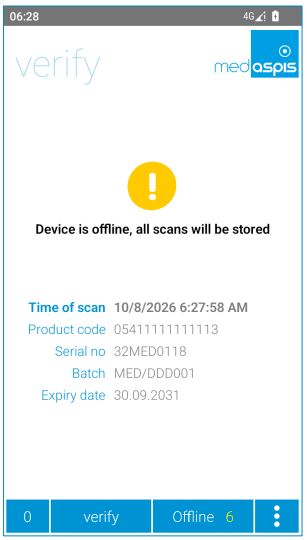
The number of records in the queue is displayed on the medAspis Speed Scanner screen. When scanning at high speed and with a slow NMVS, provided there are no technical faults, you can expect up to 5 packs to be in the queue.

2.3.3 Offline mode

Should the internet connection between the medAspis Speed Scanner and the medAspis Lean FMD System fail, data processing will be disrupted. Nevertheless, the medAspis Speed Scanner remains operational, and work does not need to be interrupted. All codes captured during the offline phase are saved within the medAspis Speed Scanner itself; under no

circumstances will any data records be lost. The number of codes captured during this phase is displayed in yellow in the bottom bar.

However, operational functionality is restricted. As there is no internet access, the data cannot be transmitted via the Lean FMD System to the relevant NMVS. No scan results are displayed in real time.



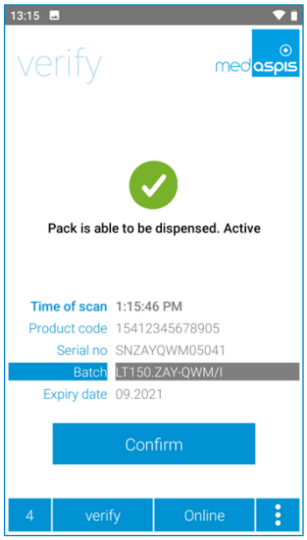
As soon as the internet connection is re-established, all data records captured and cached in the medAspis Speed Scanner will be transferred to the Lean FMD system. Depending on the volume of data, this may take a while.

Please note: Once the data has been transferred to the Scan History, it is not automatically forwarded to the NMVS. The NMVS check of the offline scans must be carried out manually in the Control Panel.

2.3.4 Batch Control

The Batch Control option can be enabled in the medAspis Speed Scanner's settings. If this function is enabled, the medAspis Speed Scanner will issue a warning if a batch or product code is scanned that differs from a reference pack.

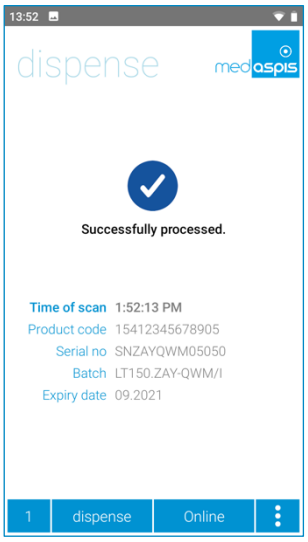
The reference pack is set by the first scan following a reset of the counter, and is displayed in the bottom left-hand corner of the medAspis Speed Scanner's screen.



2.3.5 Data capturing only

Packs can also be recorded without the data records being automatically forwarded to the relevant NMVS. To make this status clearer, the icon is displayed in blue.

The option to record data only can be set in the scanner profiles in the Control Panel.



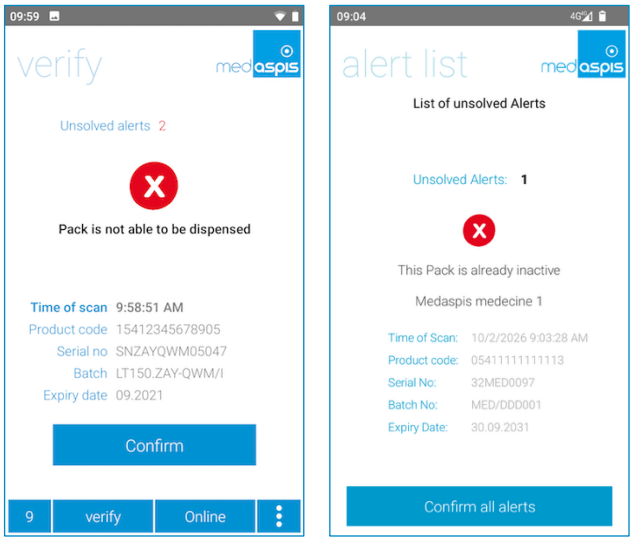
2.3.6 Reading Crypto Codes

As well as processing European FMD codes, the medAspis Speed Scanner is also capable of reading Crypto codes. These Crypto codes are commonly used in Russia and neighbouring countries; countries such as Kazakhstan also use this type of code.

The medAspis Lean FMD System cannot verify Crypto codes; it can only read them.

2.3.7 Unsolved Alert List

Every error message is stored in the 'Unsolved Alerts' list on the FMD Speed Scanner. You can access the list by clicking on the text above the error icon.



This list displays the key information for each error message in a list view. The entries include the scan date, the relevant error message and the corresponding content of the 2D matrix code (product code, serial number, batch number and expiry date).

The list can be deleted by clicking the confirmation button.

2.3.8 The Safe Dispense function

Sometimes packs are supposed to be deactivated and – surprise, surprise – the pack had already been deactivated. This double deactivation raises suspicions of counterfeiting.

To prevent such a situation – which can occur, for example, during returns processing – the Safe Dispense function is being introduced.

When this function is enabled, the actual deactivation requested is first preceded by an automatic verification check. If the pack is active, it is then deactivated as requested. However, if the pack was already deactivated, the function stops after the verification and does not deactivate the pack, as it has already been recognised as deactivated.

2.3.9 Confirm Verification Errors

As soon as the scanner detects an error, the laser switches off and the error message on the display must be acknowledged by pressing a button.

There are situations in which this procedure is cumbersome and slows down your workflow. Alternatively, you can disable this verification prompt using a toggle switch in the Speed Scanner settings.

2.4 medAspis Speed Scanner settings

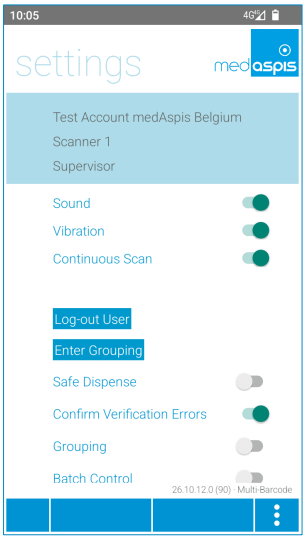
Various settings can be configured in the medAspis Connector+ app for the medAspis Speed Scanner.

The light blue box displays the connected customer account, the scanner profile and the current operator of the medAspis Speed Scanner.

Sound	enables sound playback whilst scanning
Vibration	enables vibration whilst scanning
Continuous scan	in continuous mode, the scanner is kept switched on using the side buttons or the pistol grip. 2D matrix codes are scanned continuously until the scanner is switched off manually. If continuous mode is switched off, 2D matrix codes can only be scanned one at a time.

Further settings:

Log Out User	logs the current user out. You will need to log in again to use the system next time.
Enter Grouping	prompts you to enter a new grouping.
Safe dispense	enables safe dispense through automatic verification carried out beforehand.
Confirm Verification Errors	enables error messages to be displayed during verification without the need for a confirmation prompt
Grouping	enables the grouping function
Batch Control	enables automatic batch control.



The version number of the Connector+ app is specified in the lower section of the settings. Additionally, the term “Multi-Barcode” indicates whether the matrix scan function can be used on the device.

3 Control Panel

The Control Panel is a web portal and can be accessed via the address https://panel.medAspis.org. The Control Panel logs all FMD operations that have been recorded and processed in the medAspis Lean FMD System.

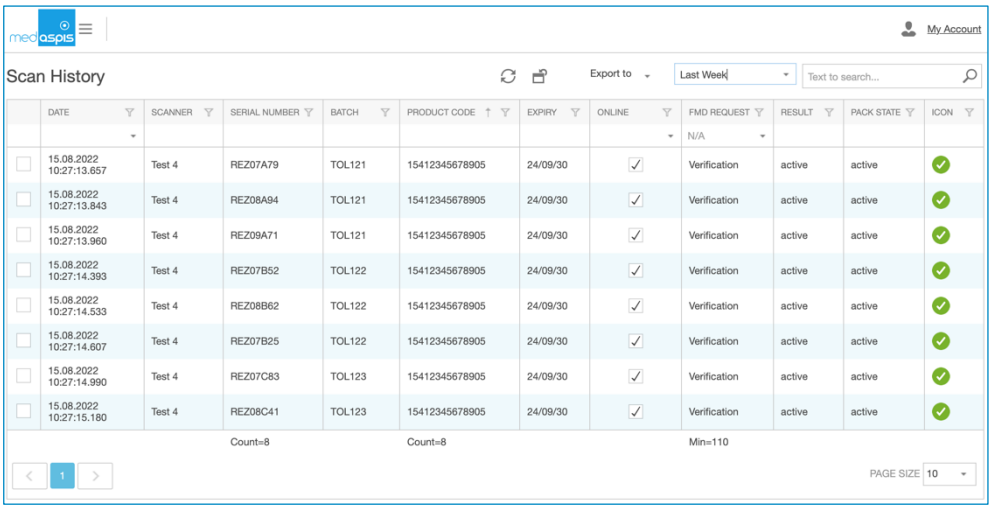
The Scan History is always displayed as the home screen. Other menu items include the Scan Archive and, optionally, Groupings and Alert Guard. The settings relate to the registered medAspis Speed Scanners, access to the NMVS and user management for the medAspis Speed Scanners.

In addition, in the top right-hand corner under 'myAccount', there are settings for your own account and the option to log out of the system.

The Control Panel has a menu bar on the left-hand side. Clicking on the three bars in the top-left corner opens the menu.

3.1 Scan History

The Scan History displays all data records captured using the medAspis Speed scanners and the corresponding NMVS results. The data is stored permanently. It is not possible to alter or tamper with the data.



3.1.1 Detailed information on each scan

For each scan, the timestamp, the pack details (product code, serial number, batch number, expiry date), the online status and the FMD result – including the current pack status – are displayed. Each entry is displayed with the same icon that was previously shown in the medAspis Speed Scanner. If the operator clicks the confirmation button following a negative result, this is also logged in the scan history.

More information is available for each data record than is shown in the scan history's default view. Values displayed in the standard view are marked with an 'x':

DATE	x	Date and time of the scan (system time)
SCANNER	x	Scanner name
PRODUCT CODE	x	Product code of the scanned pack
SERIAL NUMBER	x	Serial number of the scanned pack
BATCH	x	Batch number of the scanned pack
EXPIRY	x	Expiry date of the scanned pack
ONLINE	x	Y/N, was the medAspis Speed Scanner online during the scan?
FMD REQUEST	x	requested FMD operation to the NMVS
ICON	x	Icon for the result (see appendix)

RESULT	x	Text of the NMVS's response (full list available for download at medAspis.com)
PACK STATE	x	Pack status after FMD operation
PRODUCT NAME		Product name (optional)
CUSTOM REFERENCE		Field for free use
MAH NAME		Pharmaceutical manufacturer (optional)
NATIONAL NUMBER		national product number (optional)
USER HANDLING		Name of the operator who scanned the pack
OID		A unique key that can be used to identify the record.

The timestamp is the time recorded by the medAspis Lean FMD system. The timestamps from the medAspis Speed Scanners are not logged. This ensures that the time recording cannot be manipulated by altering the system time on the medAspis Speed Scanner devices.

After 40 days, the entries in the Scan History are transferred to the Scan History Archive for performance reasons. The Scan Archive has the same functionality as the Scan History.

There are two icons for controlling the Scan History and all other views:



Clicking on this icon will reload the contents of a table. This function is useful if new data has been created in the meantime using a scanner and has not yet been displayed.

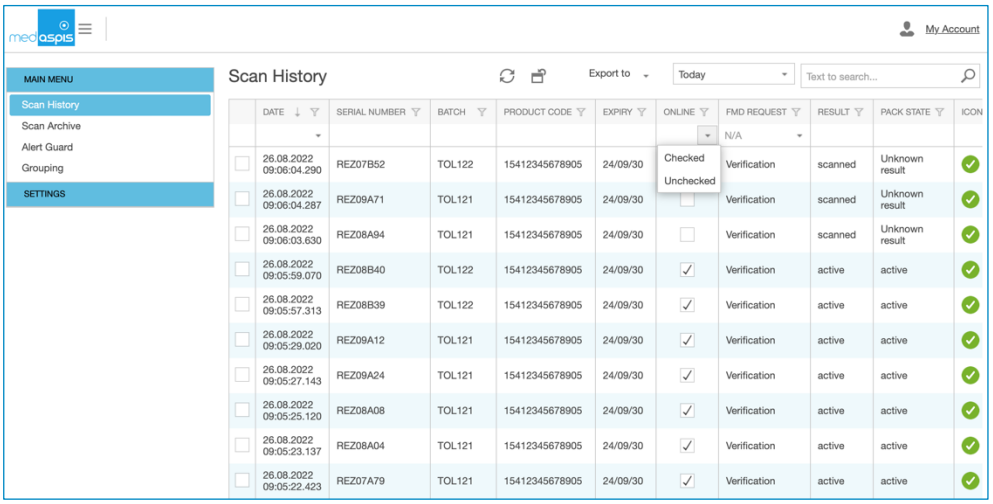


The view of tables can be changed. Clicking on this icon will reset all tables to their original view.

3.1.1.1 Offline-Mode

If a medAspis Speed Scanner does not have a direct internet connection during operation, the data for that period is temporarily stored in the medAspis Speed Scanner and uploaded to the Lean FMD system as soon as the internet connection is re-established.

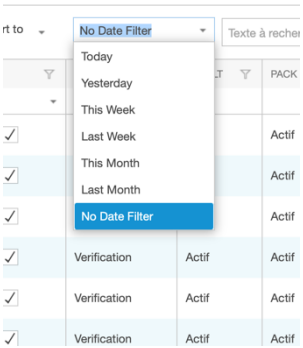
The data is displayed in the Scan History and marked as offline (not online).



DATE	SERIAL NUMBER	BATCH	PRODUCT CODE	EXPIRY	ONLINE	FMD REQUEST	RESULT	PACK STATE	ICON
						N/A			
26.08.2022 09:06:04.290	REZ07B52	TOL122	15412345678905	24/09/30		Verification	scanned	Unknown result	
26.08.2022 09:06:04.287	REZ09A71	TOL121	15412345678905	24/09/30		Verification	scanned	Unknown result	
26.08.2022 09:06:03.630	REZ08A94	TOL121	15412345678905	24/09/30		Verification	scanned	Unknown result	
26.08.2022 09:05:59.070	REZ08B40	TOL122	15412345678905	24/09/30	✓	Verification	active	active	
26.08.2022 09:05:57.313	REZ08B39	TOL122	15412345678905	24/09/30	✓	Verification	active	active	
26.08.2022 09:05:29.020	REZ09A12	TOL121	15412345678905	24/09/30	✓	Verification	active	active	
26.08.2022 09:05:27.143	REZ09A24	TOL121	15412345678905	24/09/30	✓	Verification	active	active	
26.08.2022 09:05:25.120	REZ08A08	TOL121	15412345678905	24/09/30	✓	Verification	active	active	
26.08.2022 09:05:23.137	REZ08A04	TOL121	15412345678905	24/09/30	✓	Verification	active	active	
26.08.2022 09:05:22.423	REZ07A79	TOL121	15412345678905	24/09/30	✓	Verification	active	active	

3.1.2 Working with the Scan History

The Scan History always starts with the default filter 'Today', so only scans from the same day are displayed. The list may be empty if no scans have been carried out on that day yet. You can select the desired time period simply by changing the drop-down menu. The 'No Date Filter' setting displays all entries in the Scan History. If you wish to use other time filters, you can filter by date at any time using the date column.



3.1.2.1 Sorting records

Each column in the Scan History table can be sorted by clicking on the relevant column header. The sort order is indicated by an arrow icon to the right of the column heading. Clicking again reverses the sort order.

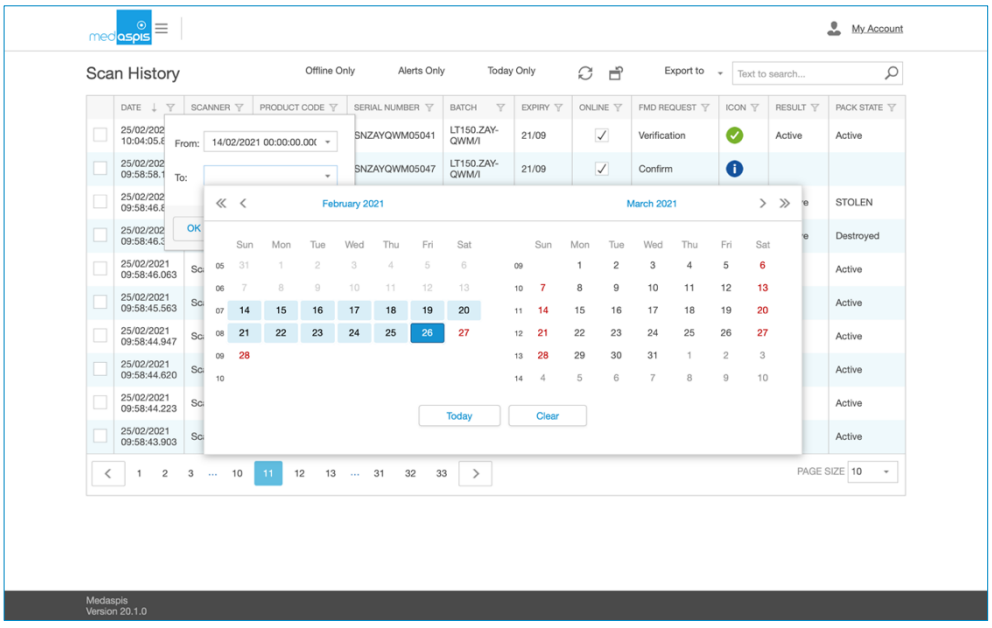
The default setting is to sort by date. The most recent entry is displayed at the top.

3.1.2.2 General filters

The data records can be filtered as required; all filters can be combined. Each column has a funnel icon next to its heading. Clicking on the funnel icon opens a window that allows you to filter the corresponding column.

The date range can be narrowed down using a start and end date. You can filter by a specific serial number, an expiry date, a pack status, etc.

Any filters you have set can be cleared by clicking the 'Clear' button at the bottom right of the screen.

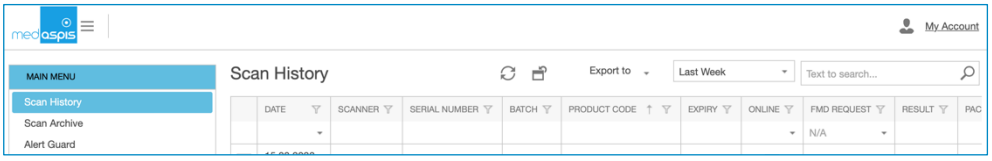


3.1.2.3 Search functions in the table

Directly below the table headings, there is a direct search function for most columns. For predefined column contents, the options can be selected directly via a drop-down context menu.

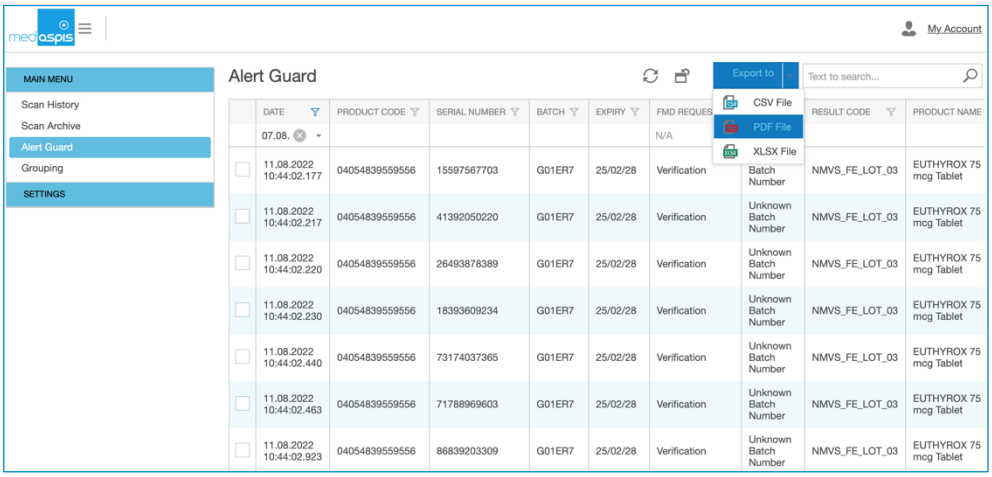
It is possible to combine filters across different columns. The selected search filters are summarised in text form in the sub-row and can be edited by clicking on the filter text. Clicking the word 'clear' will completely reset the filter at any time.

Please note: Only columns whose content can be processed by the filter can be searched, sorted or filtered. Otherwise, the column search function is not available.

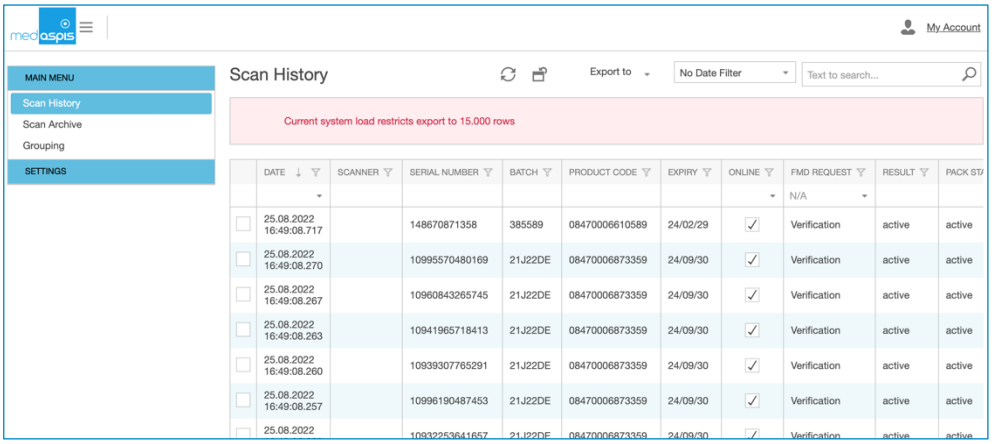


3.1.2.4 Export function

The selected and filtered data can be exported. All displayed parameters (displayed columns) and entries (displayed rows) can be exported from the system in CSV, XLSX and PDF formats. The data is made available via the browser's download function.

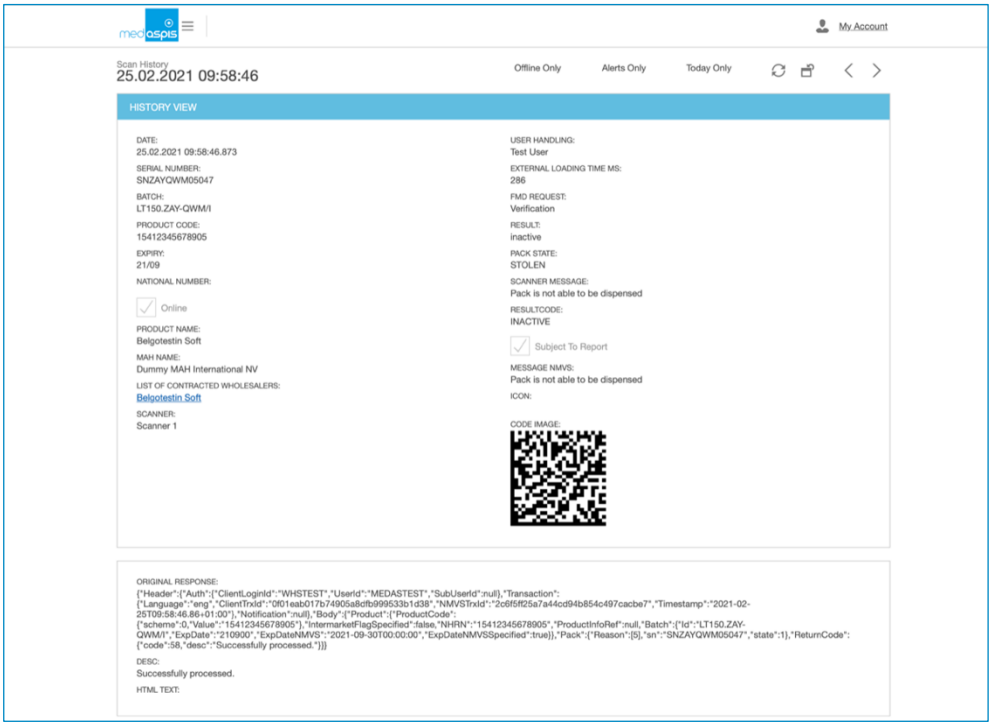


If the number of records to be downloaded exceeds the system's technical capacity, the export will not be carried out; instead, a brief message will appear with the relevant information.



3.1.2.5 Further information

For each individual scan, you can view all additional information by clicking on the relevant row.



The additional information completes the details shown in the Scan History row. Of particular note is the Code Image. This 2D matrix code contains the data from the 2D matrix code on the scanned medicine pack. This code can be used if the pack needs to be scanned again (e.g. following an offline situation).

The 'Original Response' tile contains the text file generated during the NMVS validation. If any discrepancies arise for a scan, you can check here to see how the NMVS responded to the transmission of the data record from the scan.

If specific information on alert handling is available for the scan, this is also displayed on this page.

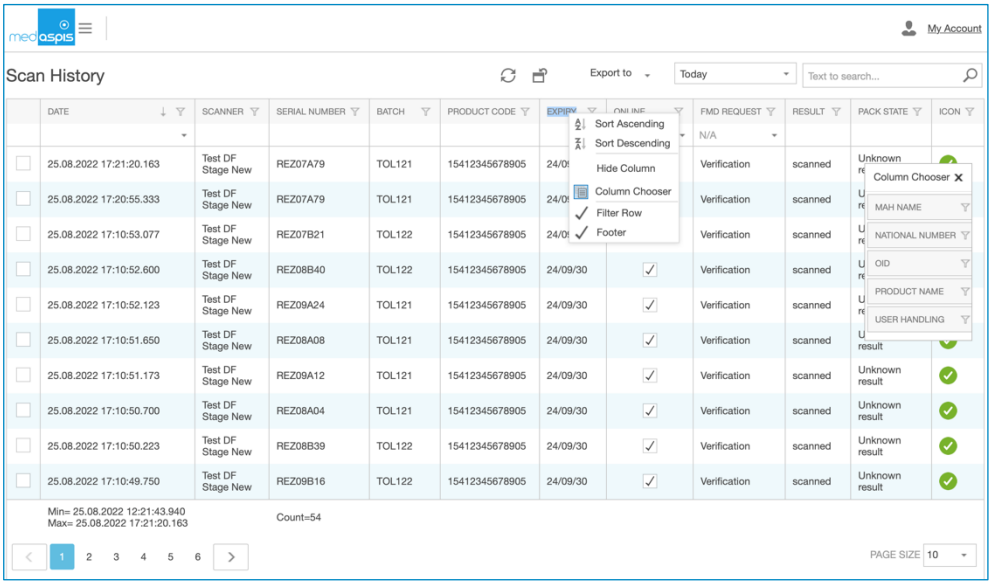
3.1.3 Scan History settings

3.1.3.1 Number of records displayed

You can choose to display 10, 20, 50, 100 or 200 lines per page. This setting can be adjusted using a drop-down menu at the bottom right-hand corner.

3.1.3.2 Visible columns in the scan history

All columns required for typical FMD operations are visible in the default view of the Scan History. Additional attributes can be displayed as required. Column visibility settings are saved and displayed permanently.



To change the layout, right-click on the table header. A context-sensitive menu will open. Two menu items control the table view. 'Hide Column' removes a selected column from the view. 'Column Chooser' opens an additional window displaying all parameters not currently shown. Drag the desired information onto the top of the table using the mouse. The selected parameter will then be displayed permanently in that position.

- Sort Ascending, Sort Descending: The column you click on can be sorted.
- Hide Column: The selected column is removed from the table
- Column Chooser: Another menu appears on the right-hand side of the page. It lists all the columns that can be displayed in addition to the existing table. To make one of these columns visible, drag the desired column header from the list using the mouse and drop it into the table at the desired position. From then on, the table will always be displayed in this modified view.
- Filter Row: This function allows you to show or hide the search field in the columns
- Footer: A new row appears at the bottom of the table. Special functions can be accessed here.

3.1.3.3 Statistical functions for the columns in the Scan History

Using the context-sensitive menu, an additional blank row can be inserted below the displayed rows (menu option 'Footer'). A further context menu can now be activated in any column of this blank row. In this menu, a counting function or the display of minimum or maximum values can be enabled.

3.2 The Scan Archive

After 40 days, to improve system performance, all data is transferred from the Scan History to the Scan Archive. All functions and views are available in the Scan Archive in exactly the same way as in the Scan History.

Please note: Reports and data downloads can only ever be generated within either the Scan History or the Scan Archive. It is not possible to download data from both views. If you require a report covering both data sources, please contact medAspis support.

3.3 Active Alert Management

medAspis's active alert management system effectively protects you from false alarms and supports you in dealing with the few remaining suspected cases. Once false alarms have been identified, they reduce the documentation burden and

keep the operational process running smoothly. The few remaining cases are reliably identified, processed and documented. The effort required to ensure compliance with serialisation regulations is significantly reduced.

The Alert Guard function is displayed in the main menu. Alert Guard is an additional, chargeable service that is only activated on a selective basis.

3.3.1 Preventing false alarms with Alert Protect

The majority of false alarms occur when medicine packs are accidentally deactivated more than once. Multiple deactivations inevitably lead to counterfeit alerts, which are forwarded to the authorities. medAspis consistently prevents these false alarms.

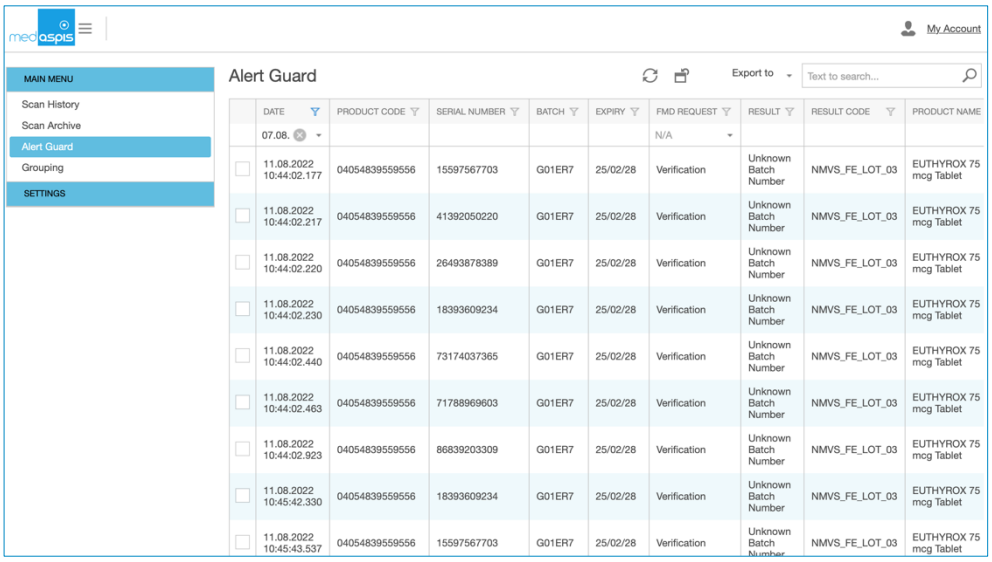
3.3.2 Double Dispense Filter

The original double-dispense filter covers a period of 10 minutes. If packs are deactivated multiple times within this period, the duplicate request is displayed as a duplicate in the scan history, but no request is sent to the NMVS. This prevents duplicate deactivations. When Alert Guard is enabled, this 10-minute period is extended to two hours.

Within this period, the same FMD operation (deactivation, export, stolen, destruction, sample, etc.) is not transmitted to the NMVS for re-verification.

3.3.3 Resolving and documenting suspected cases with Alert Guard

All suspected cases of counterfeiting are clearly presented. Guidelines are in place for scanning staff and their line managers.

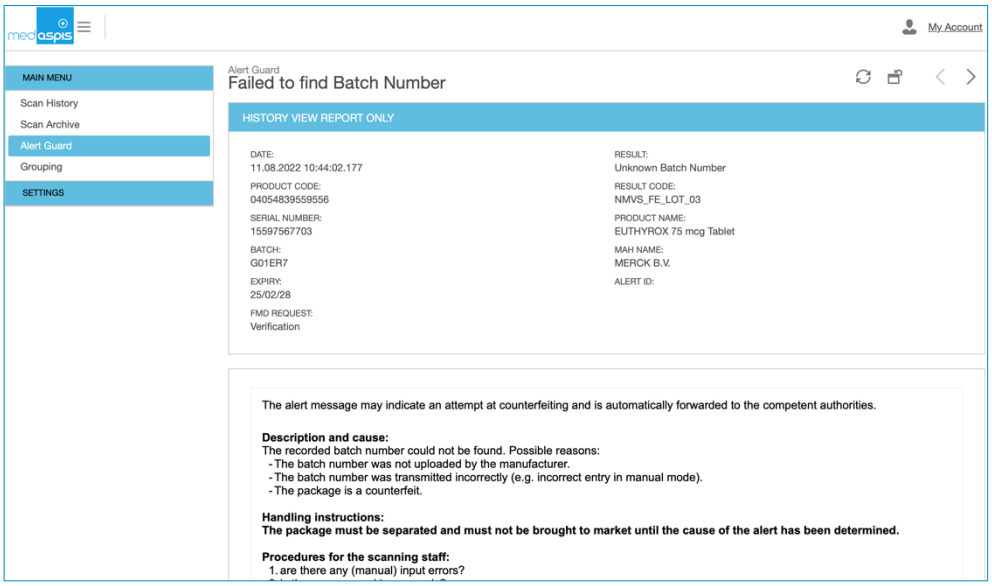


The alert overview is structured in a similar way to the scan history:

DATE	x	Date and time of the scan (system time)
PRODUCT CODE	x	Product code of the scanned pack
SERIAL NUMBER	x	Serial number of the scanned pack
BATCH	x	Batch number of the scanned pack
EXPIRY	x	Expiry date of the scanned pack
FMD REQUEST	x	requested FMD operation to the NMVS
RESULT	x	Text of the NMVS's response (full list available for download at medAspis.com)
RESULT CODE	x	The alert code specified by the NMVS (e.g. SP-201 or NMVS_LOT_03)

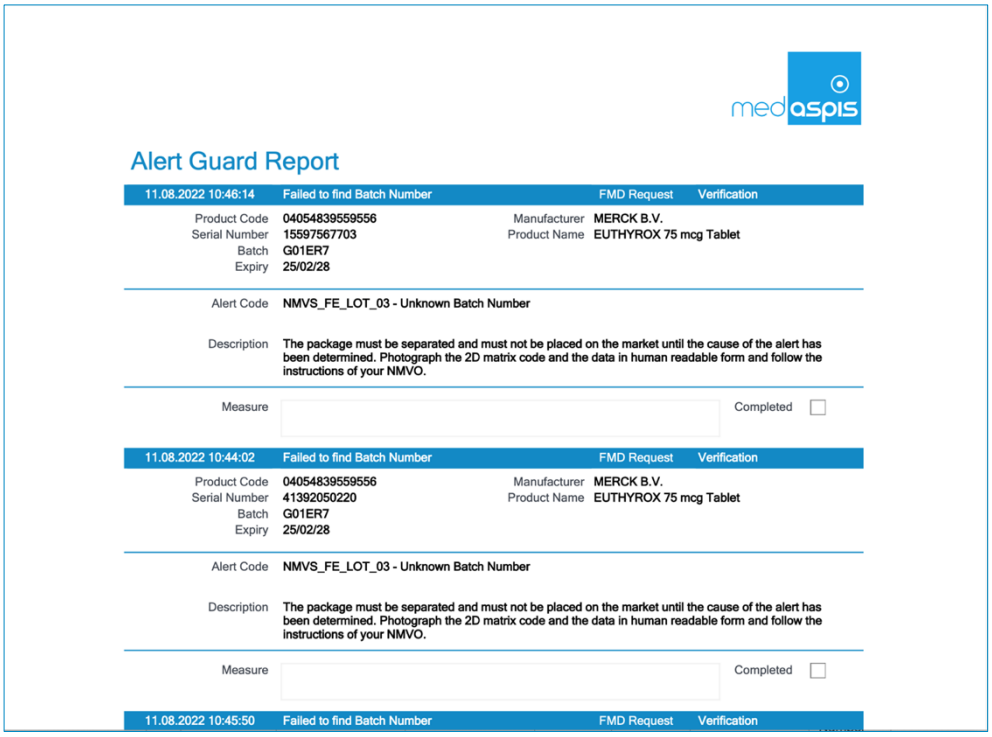
PACK STATE	x	Pack status after FMD operation
PRODUCT NAME		Product name (optional)
MAH NAME		Pharmaceutical manufacturer (optional)
NATIONAL NUMBER		national product number (optional)
USER HANDLING		Name of the operator who scanned the pack

Clicking on a row displays further details about the counterfeit alert, including detailed instructions for the scanning staff and the person in charge.



3.3.4 Alert Guard Report

From the Alert Overview currently displayed, a PDF report can be generated at any time using the export function. This report displays the key attributes of the suspected counterfeit report. Comments on the specific case can be entered in a separate field.



Alert Guard Report

11.08.2022 10:46:14	Failed to find Batch Number	FMD Request	Verification

Product Code 04054839559556 — Manufacturer MERCK B.V.
Serial Number 15597567703 — Product Name EUTHYROX 75 mcg Tablet
Batch G01ER7
Expiry 25/02/28

Alert Code NMVS_FE_LOT_03 - Unknown Batch Number

Description The package must be separated and must not be placed on the market until the cause of the alert has been determined. Photograph the 2D matrix code and the data in human readable form and follow the instructions of your NMVO.

Measure — Completed ☐

11.08.2022 10:44:02	Failed to find Batch Number	FMD Request	Verification

Product Code 04054839559556 — Manufacturer MERCK B.V.
Serial Number 41392050220 — Product Name EUTHYROX 75 mcg Tablet
Batch G01ER7
Expiry 25/02/28

Alert Code NMVS_FE_LOT_03 - Unknown Batch Number

Description The package must be separated and must not be placed on the market until the cause of the alert has been determined. Photograph the 2D matrix code and the data in human readable form and follow the instructions of your NMVO.

Measure — Completed ☐

11.08.2022 10:45:50	Failed to find Batch Number	FMD Request	Verification

3.4 Grouping operations

The medAspis Lean FMD System can not only process individual packs, but also group packs together and process them as a whole. Each group is saved under a unique name, which allows it to be retrieved and processed further in the Lean FMD System at any time.

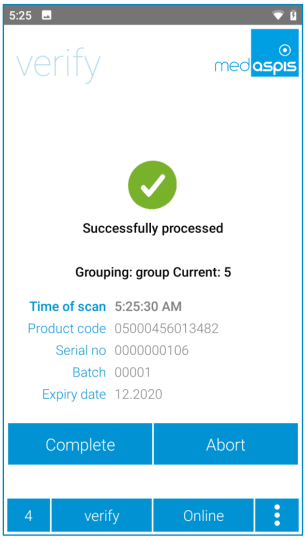
3.4.1 Groupings on the medAspis Speed Scanner

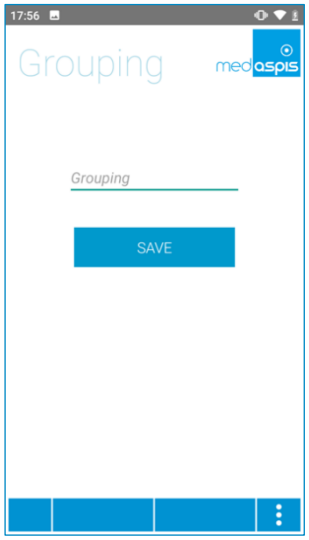
To work with groupings, the function must first be enabled in the medAspis Speed Scanner's app settings. The medAspis Speed Scanner will then prompt you to enter the name of a grouping. This can be entered using the keyboard, or the laser scanner can read a machine-readable code (barcode, QR code or 2D matrix code). Optionally, the maximum size of a grouping can be specified. This 'Max' function must be enabled by medAspis. Please contact Support.

Additional information is displayed on the medAspis Speed Scanner's standard screen. A line below the icon shows the name of the grouping and the number of packs already scanned into this group. If required as an option, the maximum size of the grouping is also displayed.

In addition, two buttons appear to complete the grouping currently in progress ("Complete") or to abort it ("Abort"). If the grouping is completed, this must be confirmed by pressing a "Confirm" button. The grouping can then be viewed in the Control Panel under the "Grouping" menu item.

All FMD functionality remains intact. FMD error messages are always treated with the highest priority.



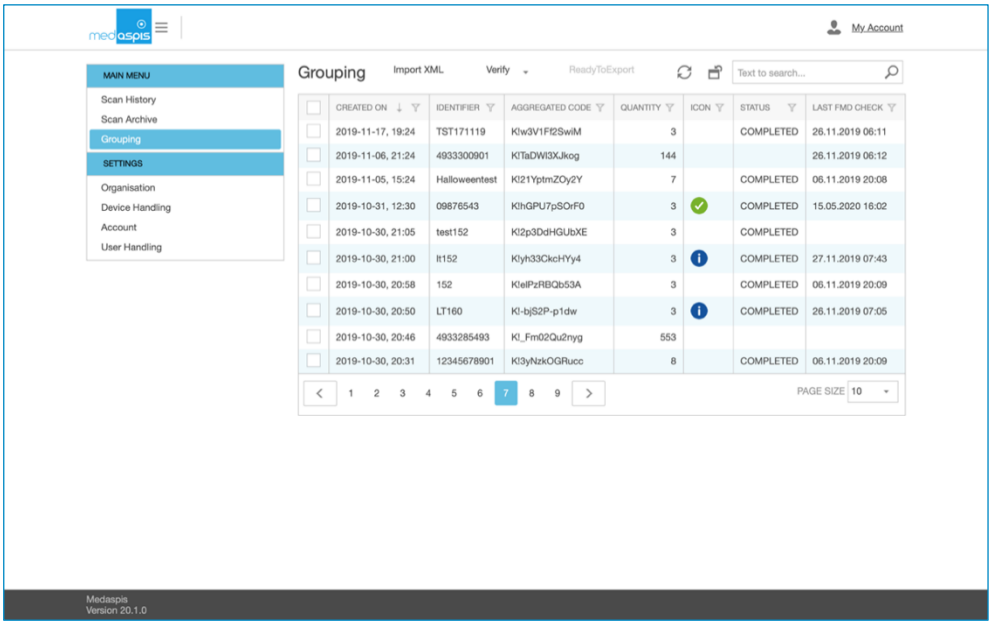


If the Batch Control function is enabled, packs with a different batch or product number will not be included in the grouping. Instead, the following error message appears on the scanner display 'Incorrect batch or PC detected. Pack will be ignored' appears on the scanner display, accompanied by a blue information icon; the scanner stops operating and must be reactivated by pressing 'Confirm'.

If the maximum group size has been specified, the scanner stops automatically as soon as the specified group size has been reached. The grouping can then be closed manually.

3.4.2 Groups in the Control Panel

Groupings have their own menu item in the Control Panel. All groupings ever created are listed there; there is no archive function for groupings.



Various parameters are displayed for each saved grouping. Values shown in the default view are marked with an 'x':

IDENTIFIER	x	name of the grouping selected by the operator
QUANTITY	x	number of packs included
ICON	x	icon of the last FMD operation on the grouping

AGGREGATION CODE	x	name (primary key) assigned by the system to the grouping
STATUS	x	current status of the group
LAST FMD CHECK	x	time of the last FMD operation carried out
LAST FMD REQUEST		most recent FMD operation requested (Verify, Deactivate, etc.)
LAST REQUEST		results icon for the last query
LAST RESULT		result of the most recent FMD operation
CUSTOM INFO 1		field for free use
CUSTOM INFO 2		field for free use
MODIFIED ON		last time the group was edited

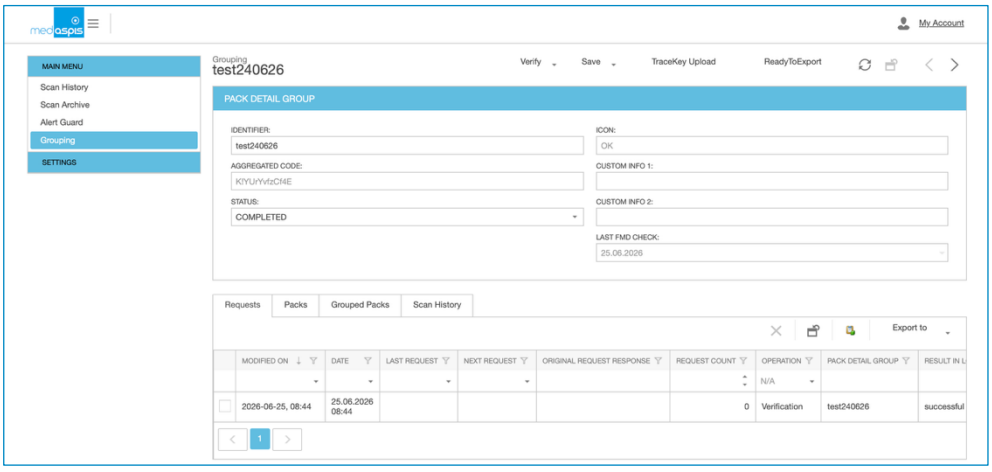
3.4.2.1 Importing groupings

Groupings can not only be created using the medAspis Speed Scanner, but can also be imported via various options in the Control Panel.

- XML file, WBDL import
  Groups can be created by importing XML files containing pack information. The XML format is described in the appendix. The German aggregation format for the Warenbegleitete Datenlieferung (WBDL) is based on this XML import.
- Importing aggregations
  Groupings can be imported using the aggregation code. If a grouping has been created in another medAspis customer account, it can be imported into your own customer account once it has been approved by changing the grouping status to EXPORT.

3.4.2.2 Detailed view of individual groupings

Clicking on an entry in the list of groupings displays detailed information about that specific grouping and allows further operations to be performed on it.



This view provides general information about the grouping:

Identifier: The name of the group is assigned in medAspis Speed Scanner. This name can be changed manually at any time in this view

Aggregated Code: The unchangeable primary key of a grouping. Specific operations relating to the groupings can be enabled via the aggregated code.

Status The current status of the group

Icon:	The icon for the last FMD operation carried out by this group. If no FMD operation has been carried out, the field remains blank
Custom Field 1:	Customers can use this field individually
Custom Field 2:	Customers can use this field individually
Last FMD Check:	Date of the last FMD operation

3.4.2.3 Status of groupings

The status describes the state of the grouping. For example: Packs can still be added to an open grouping, but a grouping with the status 'Completed' or higher cannot be changed any further.

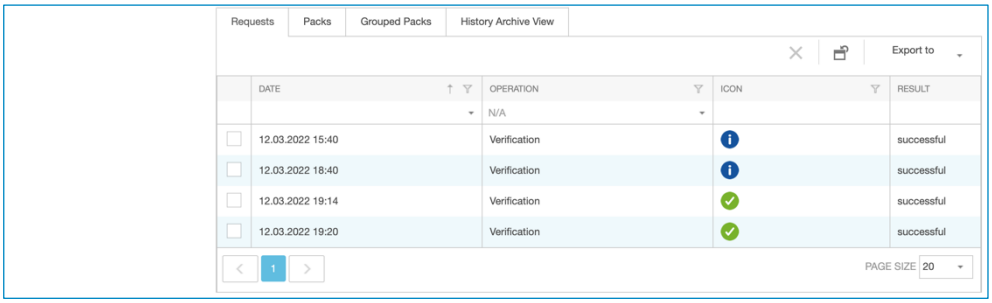
UNDEFINED	Initial state
OPEN	A grouping is currently being created using the medAspis Speed Scanner
COMPLETED	A grouping has been fully captured
VERIFIED	A grouping has been checked
EXPORT	A grouping has been exported to an external location as an aggregation
IMPORTED	A group was imported by a third party
CLOSED	The contents of a grouping can no longer be changed

3.4.2.4 Packs in a grouping

The packs in the grouping are managed via four tabs, which contain further information about the grouping.

Tab „Requests": All FMD bulk operations carried out to date for the entire grouping are displayed here. The following parameters are displayed:

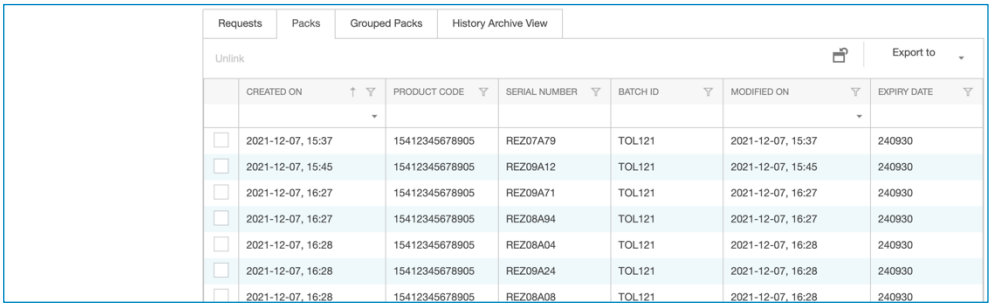
OPERATION	selected FMD operation
DATE	date of the operation
ICON	date of the operation
RESULT	result of the FMD operation



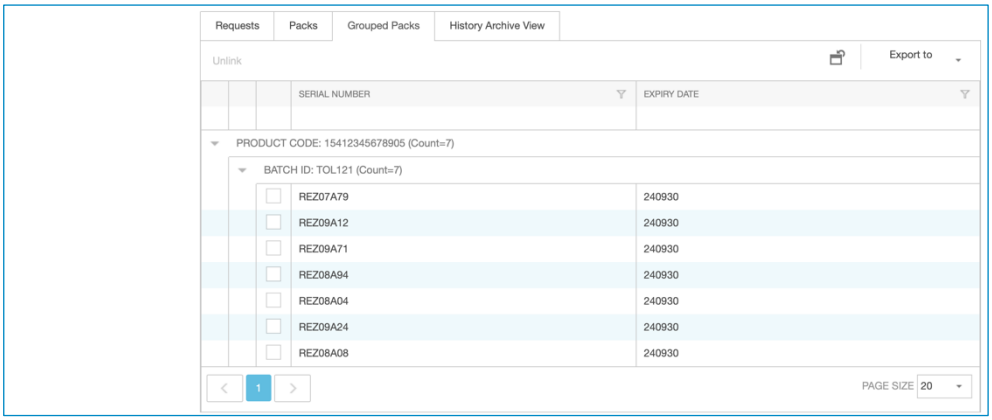
Clicking on one of the FMD operations opens a new window. An extract from the scan history is displayed here. All operations associated with the selected FMD bulk request are visible. Let's assume that a group consists of 5 packs and has been verified once and deactivated once. A total of 2 × 5 = 10 operations are then carried out: 5 for verification and 5 for deactivation.

Clicking on the deactivation option displays only the 5 deactivation operations; clicking on the verification row displays only the 5 verification operations. This view can be used to generate reports.

Tab „Packs": This tab contains a list of all the packs included. It displays the scan date and the scanned data for the packs, namely the product code, serial number, expiry date and batch number. Results of FMD operations are not displayed..

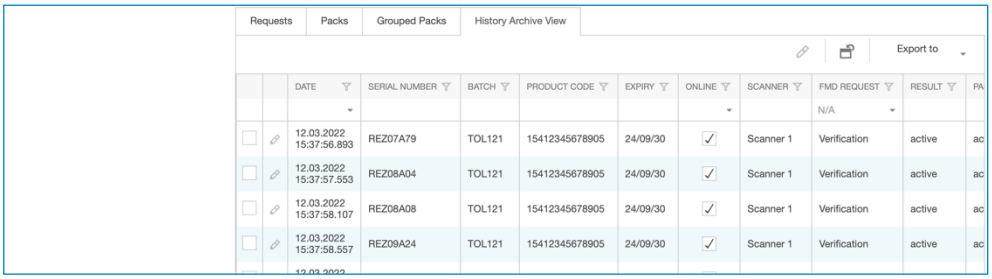


Tab: „Grouped Packs“: A list of all the packs contained, sorted by different product codes and batches. If a group is not sorted by type, you can see this at a glance here.



Tab: „History View“: This overview displays all entries in the scan history for the packs in the grouping. This list may be longer than the list in the ‘Packs’ tab, as all associated scan data (including multiple verifications, duplicate deactivations, etc.) for the packs is displayed here.

If the scanned packs have since been transferred to the scan archive, a link to the archive is automatically established. If some packs are in the scan history and others are in the archive, both assignments are displayed.



3.4.3 FMD operations on groupings

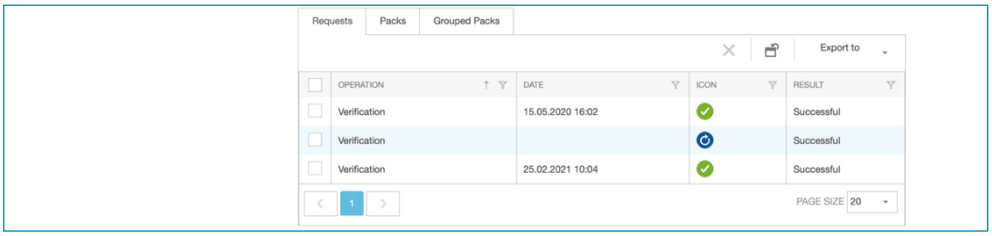
FMD operations can be carried out simultaneously for all packs within a grouping. These specific FMD operations are known as bulk operations. These bulk operations are provided by the NMVS to different extents. The medAspis Lean FMD System can only ever offer those FMD bulk operations that the respective NMVS makes available.

The checkboxes in the first column of the grouping overview are used to select the groupings for which a bulk FMD operation is intended. The FMD operations in the drop-down menu at the top of the grouping page are used to execute the desired FMD operation. The available FMD bulk operations are VERIFY, DISPENSE, EXPORT and REACTIVATE. Further FMD bulk operations can be enabled on request by contacting Support.

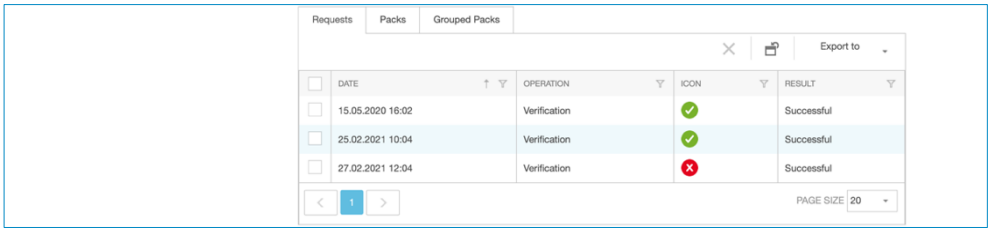
3.4.3.1 Carrying out FMD bulk operations

A grouping is applied in what is known as 'bulk mode'. In this process, the entire contents of the grouping are transferred to the NMVS in a single step. Processing takes some time; the result is not made available immediately but is held on the NMVS for retrieval.

The medAspis Lean FMD System checks at increasingly longer intervals whether the NMVS has already completed processing the grouping. As long as processing on the NMVS side is not complete, a blue icon with a rotated arrow is displayed.

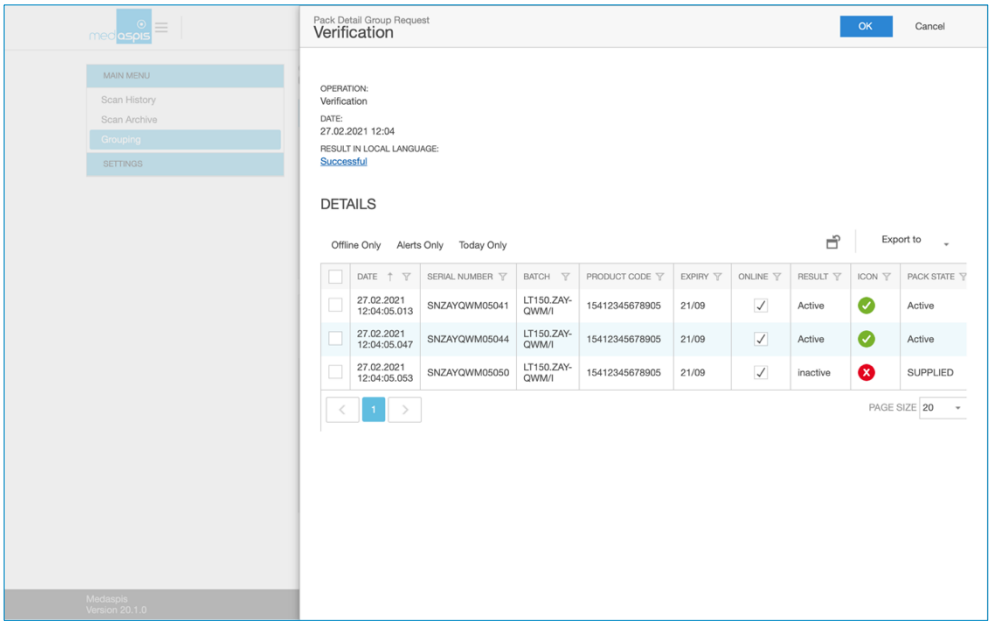


You can check whether processing on the NMVS side is complete by clicking the reload button. As soon as data processing on the NMVS side is complete and the data is available, this icon will be replaced by the results icon. The result of the bulk query will then appear in the RESULT column, along with the corresponding green or red icon.



If the FMD bulk operation returns different results for the packs within a group, the overall result will always display the most unfavourable result. Example: If, in a group of 10 packs, 7 results are marked with a green tick, 2 with a yellow warning symbol and one with a red error symbol, the red error symbol will be displayed in the group view.

Clicking on the relevant row displays all the results of the bulk operation at pack level. The sub-window that opens shows the packs contained in the grouping, along with their respective FMD results. The view and functionality are the same as in the Scan History.



3.4.3.2 Exceptions in the Arvato system during bulk processing

The blueprint provider Arvato supplies the technology for many NMVS systems (e.g. France, Poland, Spain, Italy, etc.) and handles the processing of FMD bulk operations in certain respects differently from the other two providers, Solidsoft and securPharm:

Exception: Quantity limit: Arvato does not permit more than 10,000 packs per bulk call

Exception: homogeneous bulk: for wholesalers, Arvato only permits the processing of homogeneous bulks. In these bulks, the product codes, batches and expiry date of all packs must be identical. Only the serial number may vary. Requests with mixed bulks are returned as faulty, without any results being reported for individual packs.

Exception: Returning individual pack results: As a rule, bulk operations return an individual result for each pack. Arvato has one exception to this rule: if all the packs contained in a verify bulk operation have a positive result, no individual result is returned for each pack; instead, only a single result is returned for the bulk as a whole, representing all the packs it contains.

Exception: No inter-market transactions. Arvato's FMD bulk operation does not allow the processing of packs registered in another country.

3.4.3.3 Smart Mixed Bulk Operation

To compensate for the drawbacks of Arvato's processing of FMD bulk operations, medAspis has introduced the optional Smart Mixed Bulk operation. This operation analyses a grouping before it is sent to an NMVS that uses Arvato. If it is determined that the packs are not of the same product and the same batch, the original grouping is split into homogeneous sub-segments, which are then passed to the Arvato algorithm. The individual sub-segments are processed separately and later reassembled into the grouping that was originally to be processed. The Mixed Bulk operation runs independently in the background; no separate operation needs to be called.

Unlike the original Arvato bulk operation, packs with different FMD statuses at the time of scanning can be processed (for example, one pack is active while another has already been deactivated). However, only operations permitted by the NMVS system are carried out (for example, reactivation within 10 days).

3.5 Aggregation as a special type of grouping

Aggregations are a special type of grouping. Aggregations have all the attributes of groupings, but no user-assigned name, and they can be used more flexibly.

3.5.1 Aggregation code as the primary key of a grouping

Groupings always have a primary key (a unique name). At medAspis, the primary key is a 64-bit unique identifier in Base-64 notation. In this notation, the primary key is made up of letters, numbers and common special characters. medAspis uses the characters A–Z, a–z, 0–9, + and -. It is prefixed with „K!"; an example is „K!E9j-I9S4TVI"



Every grouping – regardless of the individual name it has been given – has a primary key formed in this way. The reason: within the medAspis system, all groupings must be uniquely identifiable. It is possible, for example, that customers use the same delivery note numbers for their grouping. It is also possible that a grouping is renamed and then carries the same name as another grouping. To ensure that all groupings in the system can always be reliably identified and matched, the primary key is the aggregation code automatically generated for each grouping. This cannot be changed.

3.5.2 Hierarchical structure of aggregations

Using aggregation codes as the primary key, groupings can be organised hierarchically. Aggregations can be part of a higher-level aggregation. This hierarchical relationship can extend across any number of levels.

3.5.3 Exporting aggregations

Aggregations can be made visible to third parties, allowing complete groupings to be transferred from one customer to the next. When the status of an aggregation is set to EXPORT, the aggregation becomes visible to other users of the Lean FMD system and can be incorporated into their own data structure. Aggregations are passed on, for exam-ple, by attaching the aggregation code to a medicine carton or a pallet. The recipient sees the code, scans it, and has thereby incorporated the data into their own data structure.

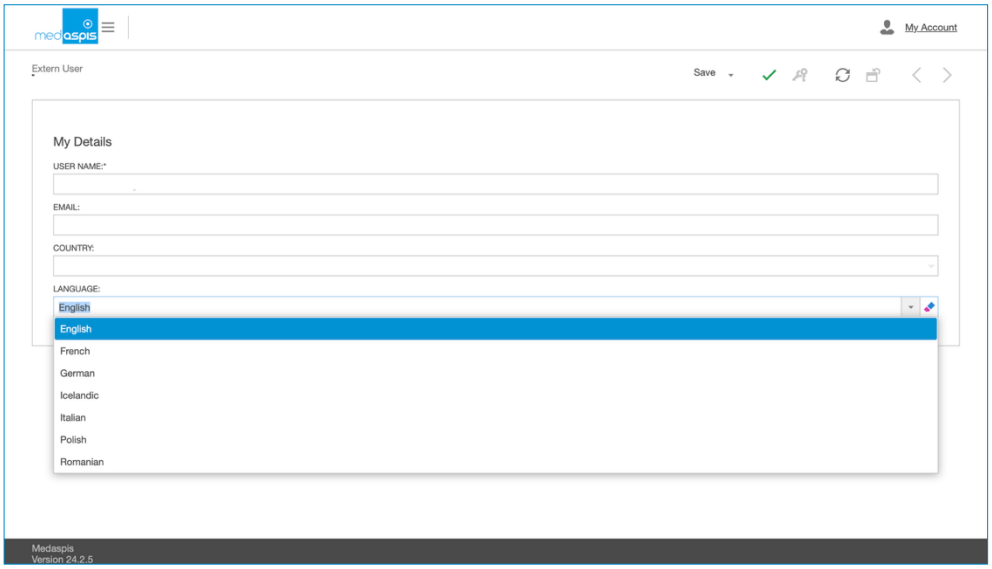
3.5.4 Aggregation codes as labels

To simplify the processing of aggregations, medAspis supplies its customers with lists of aggregation codes. These can be printed on standardised sticker sheets with 27 (3 x 9) codes per sheet.

4 Maintenance of the Lean FMD System

4.1 Managing your own account

By clicking the „My Account“ link at the top right, you can log out of the system or configure basic attributes for the system.



The name of the customer account and the country are assigned in advance and can no longer be changed. Other attributes, such as the e-mail contact or the system language, can be adjusted in this view. Some changes only take effect the next time you log in to the system.

4.1.1 Password complexity

When using the Lean FMD system for the first time, you can change the temporary password to a password of your own choice. The password shouldn't be too simple; it must meet a certain level of complexity. How this complexity is achieved is up to you. Generally, the following factors are taken into account when calculating the password’s complexity:

- Password length
- Use of upper-case and lower-case letters
- Use of special characters
- Use of numbers

There is no rule stating that you must use all of the above elements of complexity. A password can be complex enough even if you do not use any special characters, provided that its length alone ensures sufficient complexity.

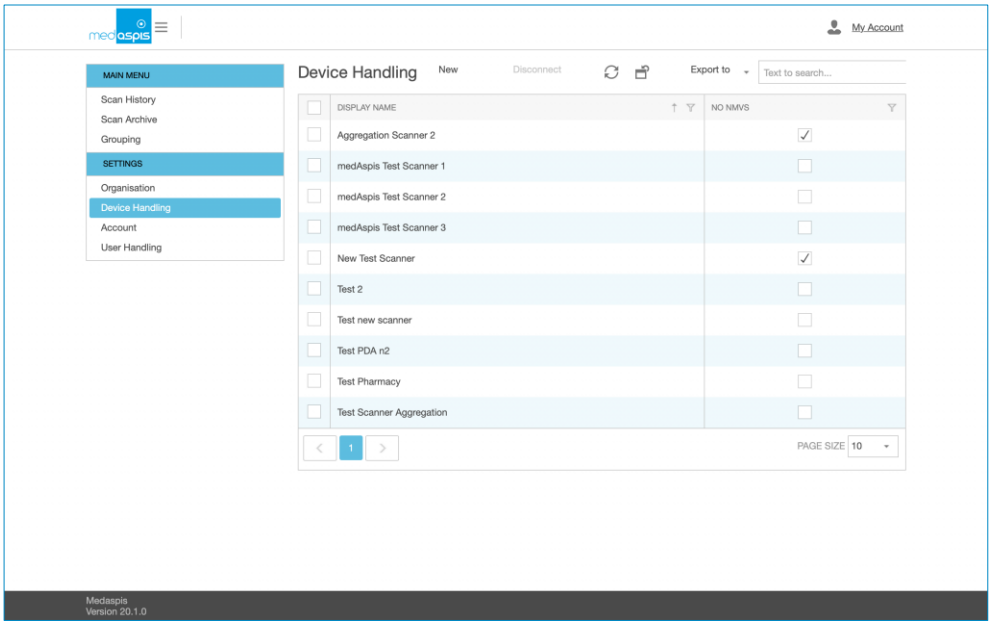
You can request a new password at any time via medAspis Support.

4.2 Registering a medAspis Speed Scanner to your own customer account

Registering a medAspis Speed Scanner with the system requires several steps in the Control Panel and in the medAspis Speed Scanner's software.

4.2.1 Creating a profile for a medAspis Speed Scanner

Every medAspis Speed Scanner that is to be used under a customer account must be registered once. To do this, an existing scanner profile is selected, or a new scanner profile is set up, in the Control Panel under the „Device Handling“ menu item.

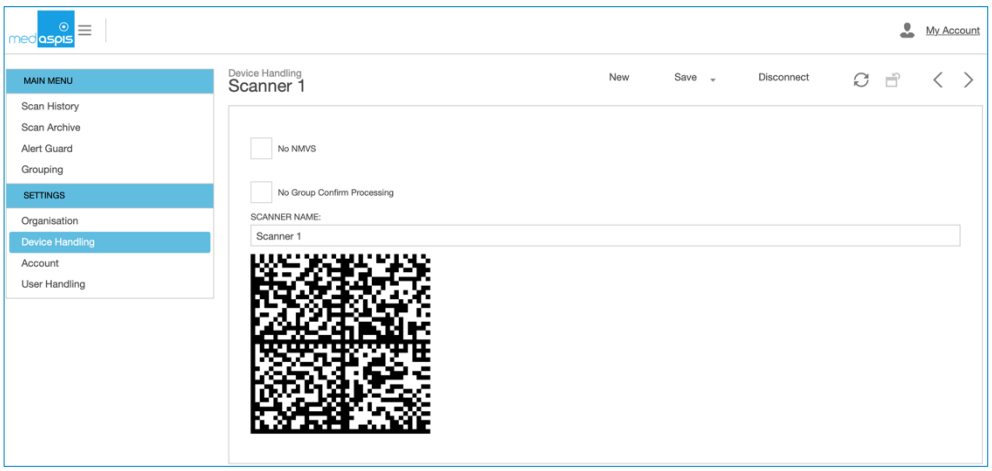


Once the window is open, you can see all the scanner profiles created so far. The scanner profiles are displayed with their name and, optionally, additional parameters. Multiple medAspis Speed Scanners must never be registered under the same scanner profile.

For reasons of data integrity, a scanner profile cannot be deleted once it has been created. However, not every scanner profile shown has to be connected to a medAspis Speed Scanner. If a medAspis Speed Scanner is defective and needs to be replaced, the new medAspis Speed Scanner replacing it can be operated under the same scanner profile. If a new device is purchased in addition to existing devices, a new scanner profile must always be created.

4.2.1.1 Creating a new scanner profile

A new scanner profile can be created using the „New“ button.



Three fields must be specified for the new scanner profile:

NAME:	The name of the scanner profile. This name is later visible in the settings menu of the connected scanner, and scans appear in the Scan History under this scanner name.
No NMVS:	If this field is ticked, the scanned data is not transmitted to the NMVS. With this option, 2D matrix codes are captured in the Lean FMD system but are not passed on to the NMVS.
No Group Confirm Processing	As a rule, no further packs can be added to a grouping once it has been closed. Activating this function removes this restriction, allowing groupings to be extended at any time.

The process is completed using the „Save“ button. A large enrolment code appears on the screen. This must be read by the medAspis Speed Scanner to be connected during the enrolment process, in order to connect it to your own system via the scanner profile.

4.2.1.2 Making changes to a scanner profile

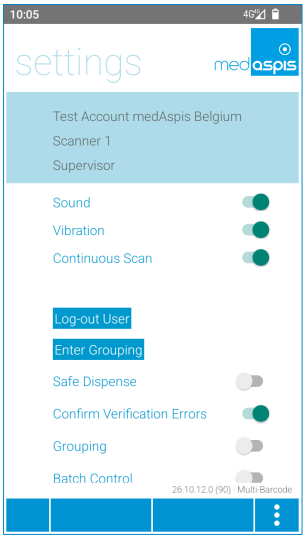
One of the existing scanner profiles is selected. Alongside the stored attributes, a large enrolment code appears on the screen. All stored attributes can be changed. To apply the changes, the SAVE button must be pressed first. However, these attributes are only transmitted to the medAspis Speed Scanner the next time it logs in.

Saving also changes the large enrolment code. To transfer the new attributes to a medAspis Speed Scanner, the enrolment process must be run on the handheld device to read the new enrolment code onto the relevant medAspis Speed Scanner.

4.2.2 Connecting a medAspis Speed Scanner to the scanner profile

To register a medAspis Speed Scanner to a customer account, the scanner profiles under the „device handling“ menu item are used. To register a medAspis Speed Scanner, first open a scanner profile or create a new scanner profile.

If the medAspis Speed Scanner is not in registration mode, please go to the app settings (menu at the bottom right of the medAspis Speed Scanner's display) and press the medAspis logo five times. The medAspis Connector+ app immediately starts the mode for registering to a new scanner profile.

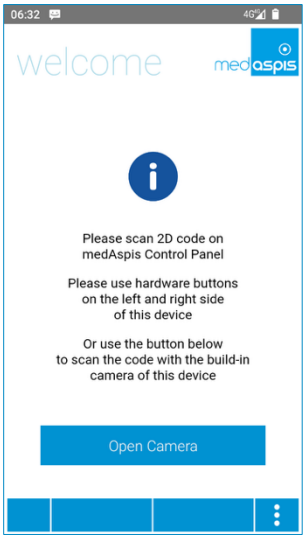


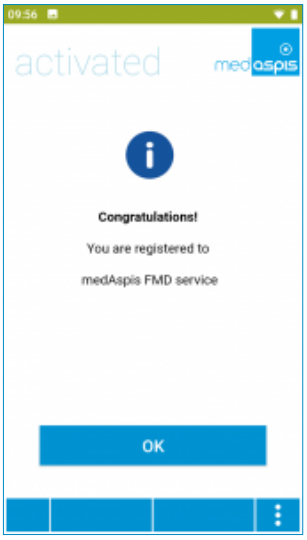
CAUTION: this method disconnects the medAspis Speed Scanner from its existing connection to the Lean FMD system, and it can no longer be used in its previous area of operation.

The enrolment code is now captured with the medAspis Speed Scanner from the screen showing the desired scanner profile. The enrolment code can be captured using the laser scanner. In this case, simply scan the enrolment code with the medAspis Speed Scanner.

If the scan does not work (for example, on highly reflective screens), the built-in camera can be used instead. In some cases, the Pistol Grip needs to be released for this. Then the Open Camera button must be pressed. Using the resulting camera image, the enrolment code is filmed from the screen.

As soon as the enrolment code has been recognised (scanner or camera), the connection between the medAspis Speed Scanner and the scanner profile is established. After a second confirmation screen, a "Congratulations Screen" appears and the medAspis Speed Scanner is connected to your medAspis Lean FMD system.



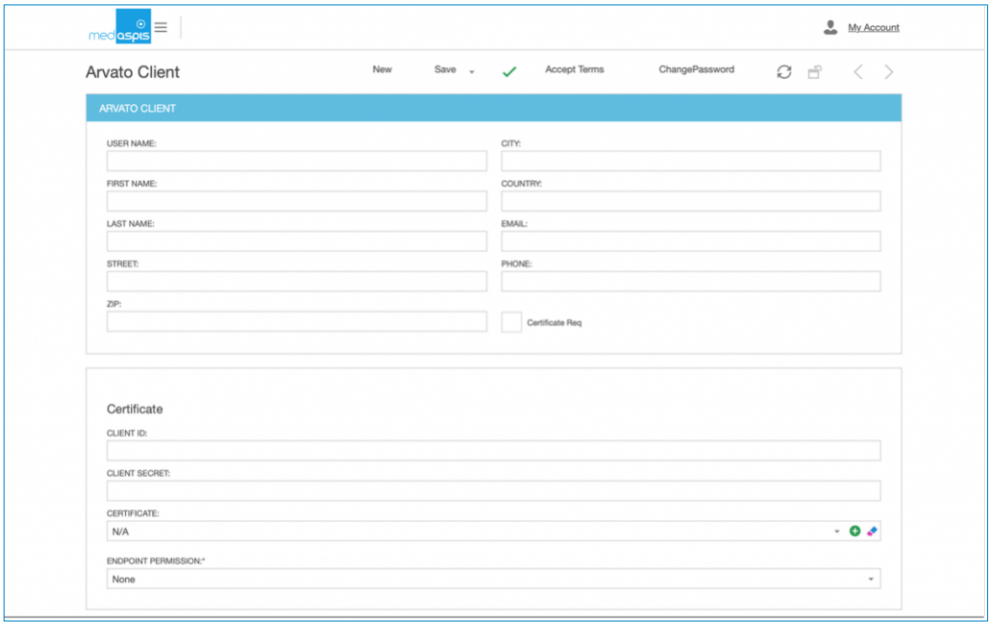


4.3 Register with the NMVS

To be able to carry out FMD operations, the medAspis Lean FMD system must be connected to the responsible NMVS. Three different systems are in use in Europe. medAspis can be connected to all three systems (securPharm, Arvato, SolidSoft). Each of these so-called three blueprint systems requires its own registration steps.

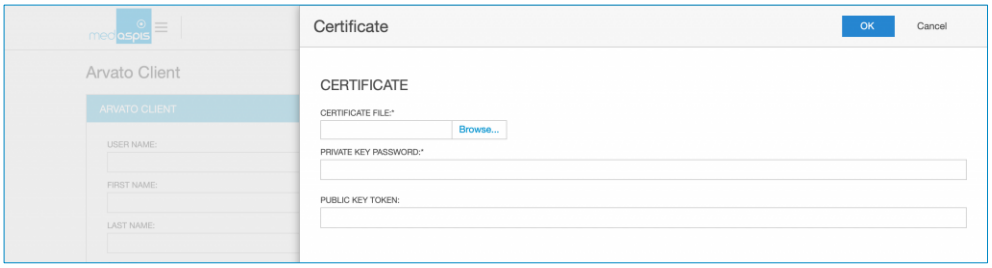
4.3.1 Access to the Arvato system

This system is used in Austria, Belgium, Cyprus, Estonia, Finland, France, Italy, Latvia, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Hungary, and the United Kingdom (Northern Ireland).



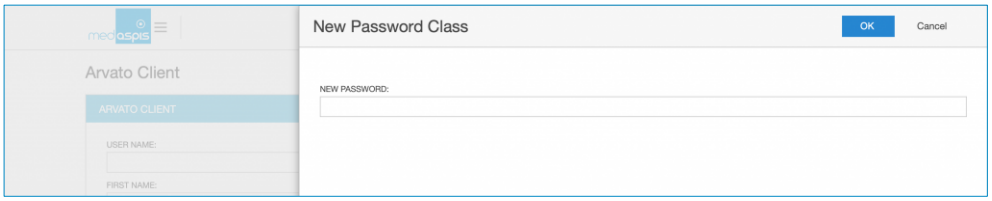
The access data required for this step must be obtained from the responsible NMVS. First, enter all the data received into the relevant text fields, then, in the „Certificate" section, enter the username and initial password received from the NMVO.

The certificate is then downloaded. First, the certificate window is opened by clicking the „plus" icon.



The certificate file (.p12) previously provided by the NMVO is uploaded, and the certificate password and password token are entered. Both items are provided by the NMVS. The certificate window is closed with OK, and the whole process is completed with „Save".

Then, in the Arvato main window, Arvato's „Terms and Conditions" are confirmed and the initial password is changed. Buttons for both actions are available at the top of the window.

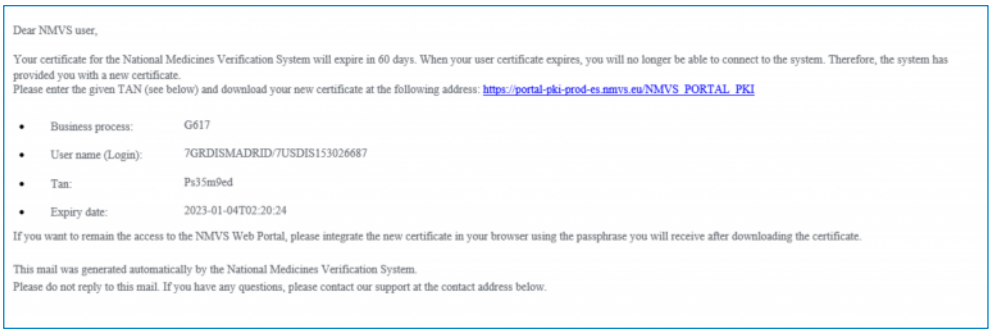


The new password is confirmed with OK. The password window closes.

The process is complete; the system is connected to the responsible NMVS.

4.3.1.1 Renewal of an Arvato certificate

From time to time, the access certificates must be renewed. You must request a new certificate from your NMVO. In the example presented here, this is SEVeM, the Spanish NMVO. In this case, the response consists of a username, a TAN code and a URL.



Dear NMVS user,

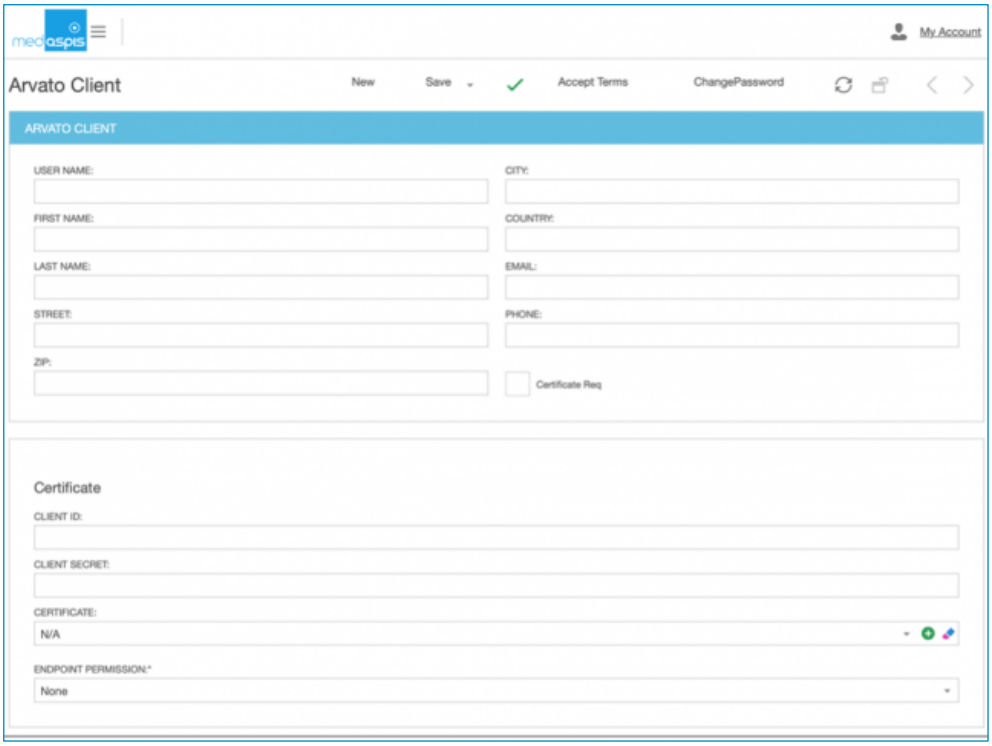
Your certificate for the National Medicines Verification System will expire in 60 days. When your user certificate expires, you will no longer be able to connect to the system. Therefore, the system has provided you with a new certificate.
Please enter the given TAN (see below) and download your new certificate at the following address: https://portal-pki-prod-es.nmvs.eu/NMVS_PORTAL_PKI

- Business process: G617
- User name (Login): 7GRDISMADRID/7USDIS153026687
- Tan: Ps35m9ed
- Expiry date: 2023-01-04T02:20:24

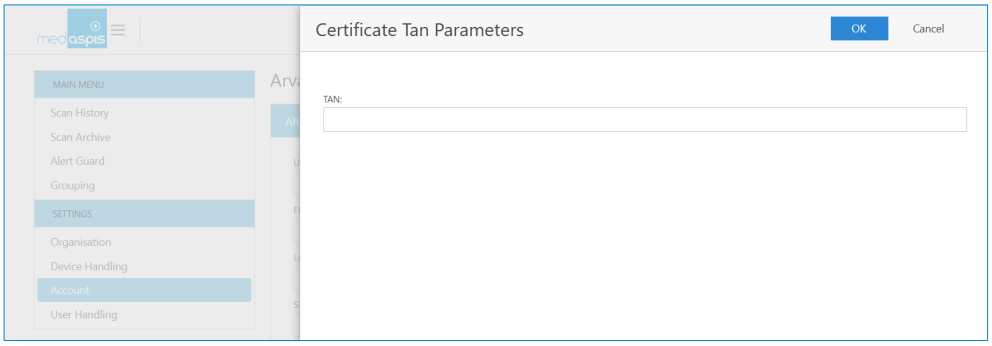
If you want to remain the access to the NMVS Web Portal, please integrate the new certificate in your browser using the passphrase you will receive after downloading the certificate.

This mail was generated automatically by the National Medicines Verification System.
Please do not reply to this mail. If you have any questions, please contact our support at the contact address below.

From this point on, the process continues in the medAspis Control Panel. Please go to the Account tab in the menu. Make sure that the fields under „Certificate" are filled in with your valid client ID and your client secret (your NMVS login details). Please click „Update certificate".



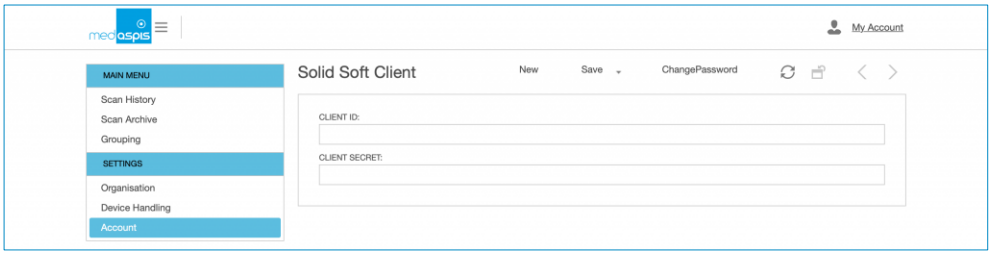
In the following window, enter the TAN you received earlier and click „OK".



Please do not forget to complete the process by clicking the „SAVE“ button at the top of the screen. You have now set up your new certificate.

4.3.2 Access to the Solidsoft system

This system is in use in Bulgaria, Denmark, Ireland, Iceland, Croatia, Liechtenstein, Lithuania, Sweden, Switzerland, Slovakia and the Czech Republic.

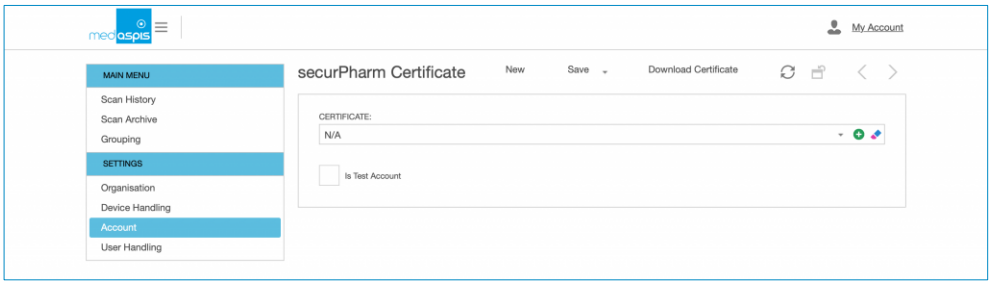


The access data required for this step must be obtained from the responsible NMVS. The „Client ID“ and the „Client Secret“ are entered and saved using the „Save“ button.

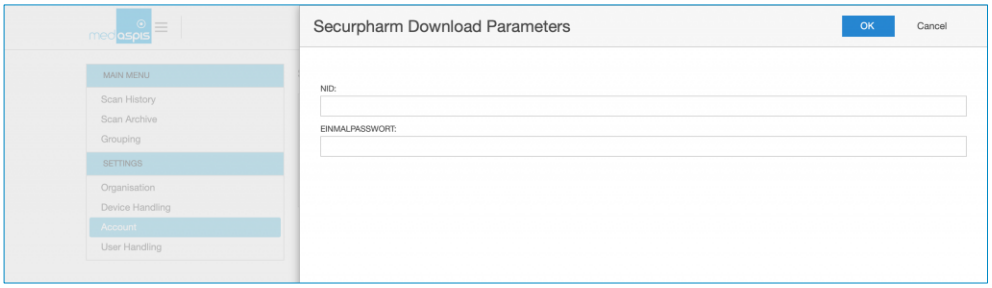
The process is complete; the system is connected to the responsible NMVS.

4.3.3 Access to the securPharm system

This system is only used in Germany.



First, the „Download Certificate“ button is used to open a new window in which the securPharm certificate can be loaded. To download the certificate, the customer has received a so-called establishment number, the N-ID (format APOxxxxxxxx), and a password from the NMVO. Both values are entered into the relevant fields and confirmed with "OK" at the top of the window.

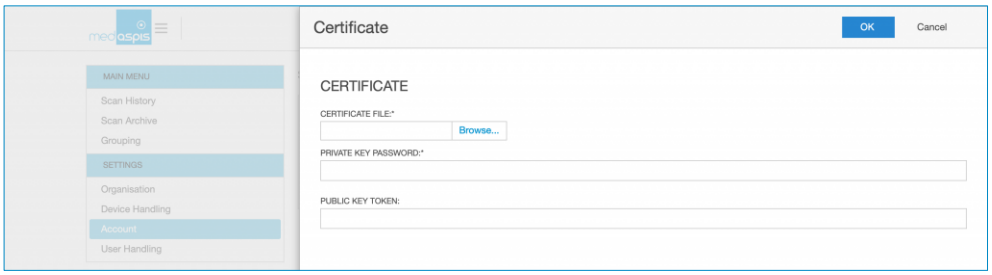


The window closes again and the certificate, now downloaded from the NMVS, is displayed. The process must now be saved in the securPharm main window using the „Save“ button at the top of the window.

4.3.3.1 Alternative registration

If you have already downloaded your certificate yourself from NGDA, you will have a file named after your establishment number with the suffix ".p12" (APOxxxxxx.p12).

Please first click the green plus icon on the "Certificate" input field. A new window opens:

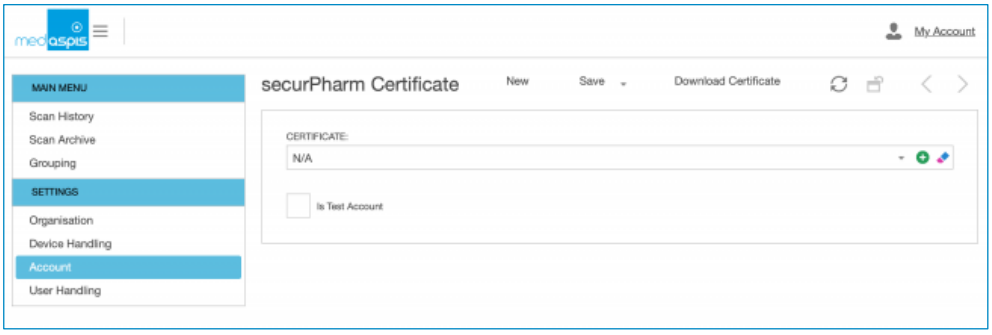


In this window, the certificate can be uploaded; the associated password must be entered, and the "PUBLIC KEY TOKEN" field must be left blank.

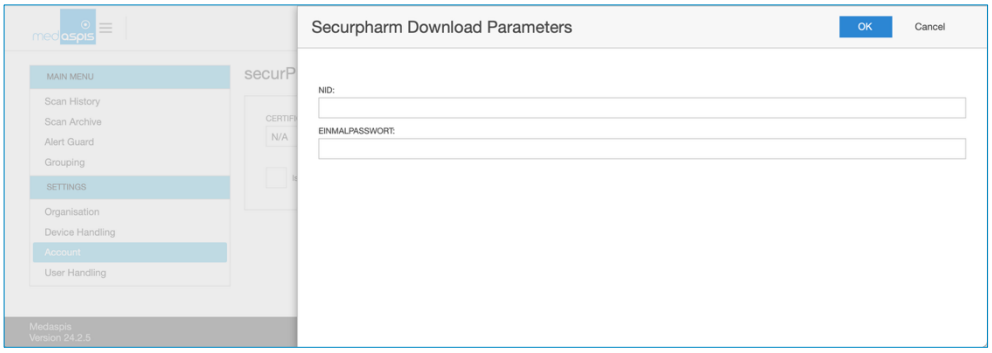
The process is complete; the system is connected to securPharm.

4.3.3.2 Renewal of a certificate

From time to time, the access certificates must be renewed. The renewal of your certificate is requested via the NGDA portal. You will then receive a letter from NGDA containing a TAN, which you can now use in your medAspis Control Panel. You will find the required field in the Control Panel menu under the securPharm Access tab.



Clicking „Download Certificate“ here opens a window asking for your NID (establishment number in the format APOxxxxxx) and a one-time password. In the latter field, enter the password received from NGDA and click OK. The certificate is installed automatically.



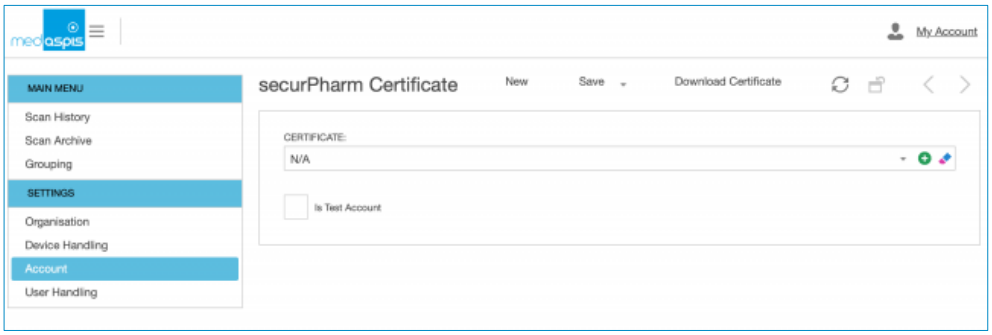
Once these changes have been saved, the new certificate is activated and linked to the customer account.

Download the certificate yourself:

If you have already downloaded the certificate (.p12 file) via the NGDA portal, you can also add it directly as a file in your Control Panel.

To do this, please click the green „+" icon under Control Panel/securPharm Access, „browse" your PC for the certificate, and enter the certificate password in the „Private Key Password" field. The „Public Key Token" field should remain empty.

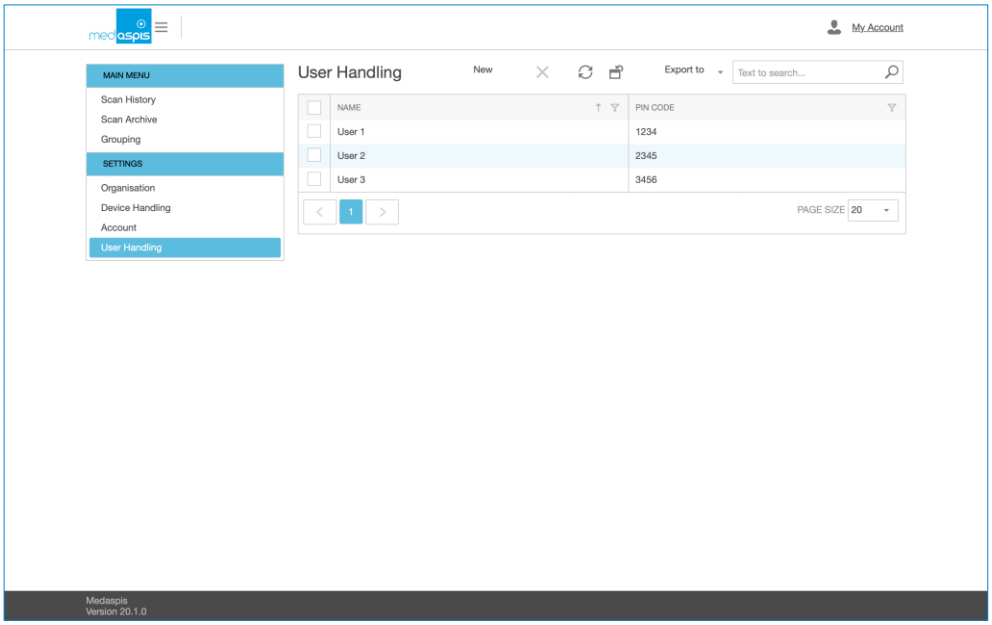
Save the changes, and the new certificate is now activated and linked to your account



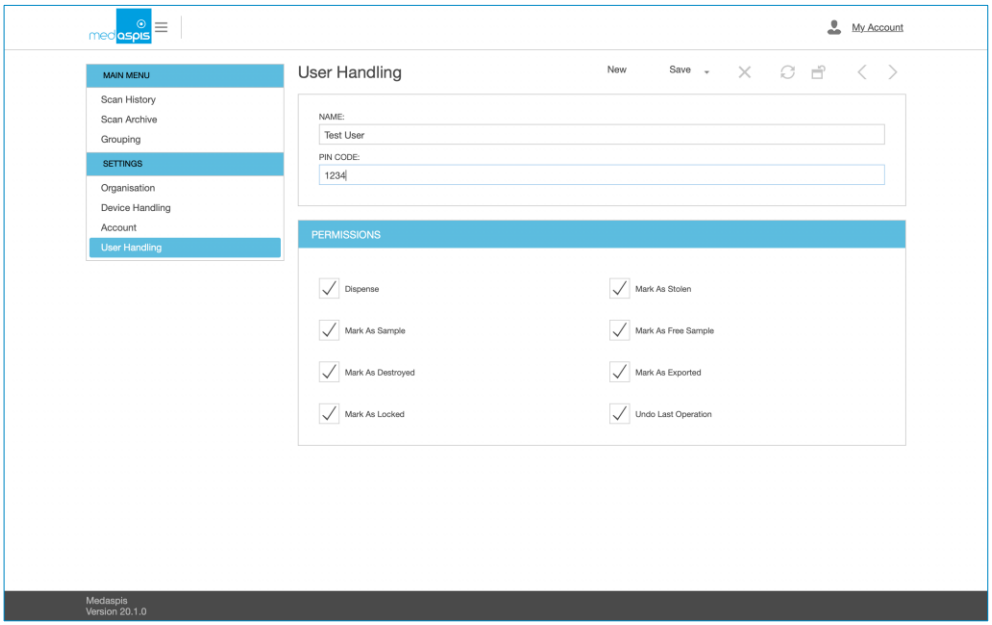
Please do not forget to complete the process by pressing the SAVE button. The new certificate is now installed.

4.4 -User Handling for the medAspis Speed Scanner

The medAspis Lean FMD system can optionally manage different operators of the medAspis Speed Scanners. Every time an operator scans packs, the operator's name is stored alongside that scan. The names can optionally be displayed in the Scan History.



A new operator can be created using the „New“ button.



To do this, a name and a numeric PIN code of any length are entered. The name is displayed in the app settings of the medAspis Speed Scanner and, optionally, in the Scan History. The PIN code is requested on the handheld scanner as an identity check. In addition, the permitted FMD operations can be restricted for each operator.

Once complete, the entries are saved using „Save“.

User handling is an identity check and thus a measure for organising operational workflows. User handling does not constitute a function in terms of system security.

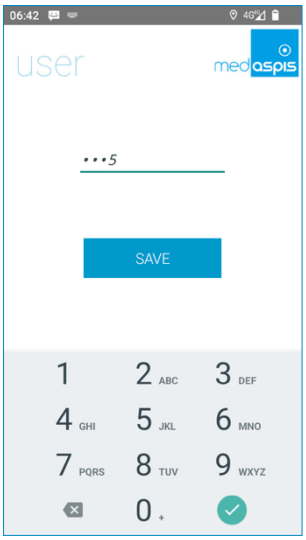
4.4.1.1 Access rights

Individual usage rights can be granted for each operator. Only the FMD operations permitted in the "Permissions" field are displayed in the handheld scanner's FMD menu; the others are not offered at all. This can be very useful for preventing

the unintended execution of unwanted FMD operations (for example, „mark as stolen“ or „mark as destroyed“) on the medAspis Speed Scanner.

4.4.1.2 In use on the medAspis Speed Scanner

An operator can only use the medAspis Speed Scanner after entering the correct PIN code. The PIN code is masked with dots whilst it is being entered.

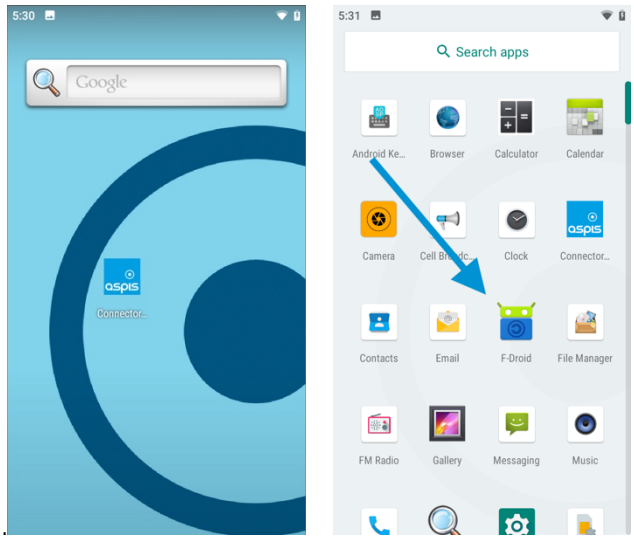


4.5 Updating the medAspis Speed Scanner via F-Droid

4.5.1 Manual software update

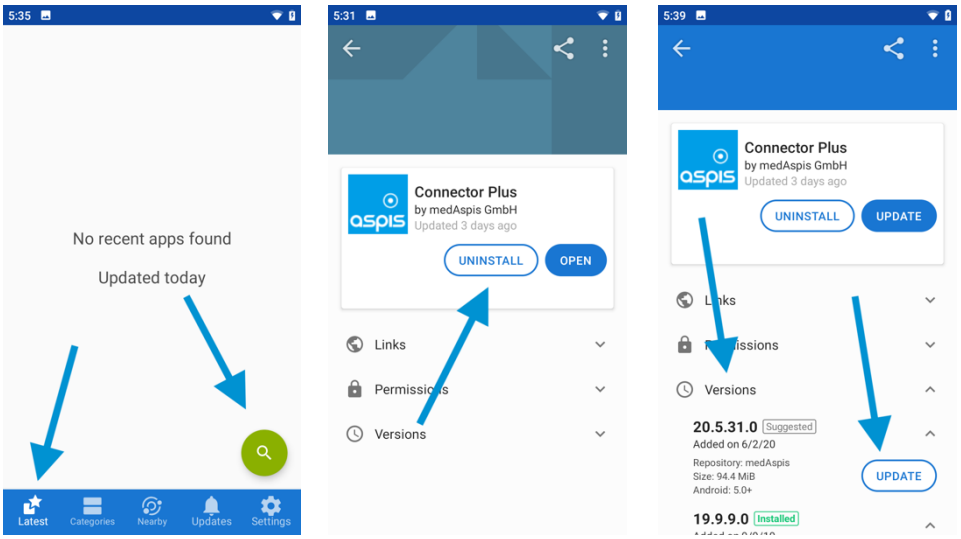
medAspis regularly releases updated versions of the medAspis Connector⁺ app. The system continuously checks for updates and can optionally install them automatically. Below you will find instructions for manually updating the software.

On the medAspis Speed Scanner's home screen, simply swipe upwards to open the list of programs on the device (Android users will be very familiar with this)



Select the 'F-Droid' application. This program is responsible for updates to the medAspis Connector+ app.

After opening the F-Droid app, you should see the medAspis Connector+ app on the screen; if not, press 'Latest' in the bottom row. If you still cannot see the medAspis Connector+ app, try the search function at the bottom right and search for 'medAspis'. The app will then become visible.



Tap on the medAspis Connector+ app; details of the medAspis application appear.

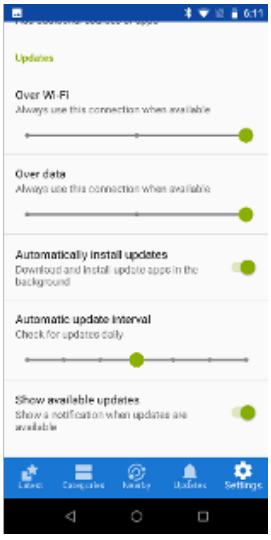
You will then be asked whether you want to uninstall or open the medAspis Connector+ app. Please choose to uninstall it and complete the uninstallation process. Don't worry, the application is not lost; a fresh version will be loaded.

Afterwards, please click 'Versions'. Several versions are displayed for you to choose from. Tap the top version labelled "suggested" (this is always the most recent version).

Tap 'Install' and follow the installation instructions.

4.5.2 Automatic software update

Open F-Droid (as with the manual software update) and click on Settings. A page opens that looks like the one shown below. Scroll down until you reach the „Automatically install updates“ entry.



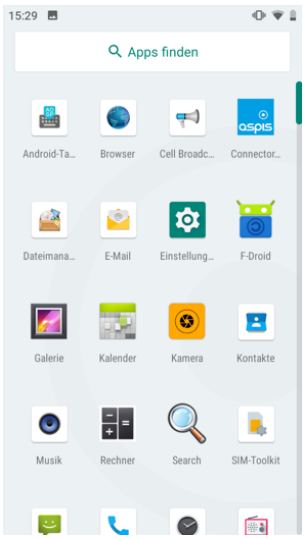
Configure the automatic update in line with the settings shown in the image. Make sure the medAspis Speed Scanner remains connected to the internet. As soon as a new version of the software becomes available, F-Droid will register it and update the application.

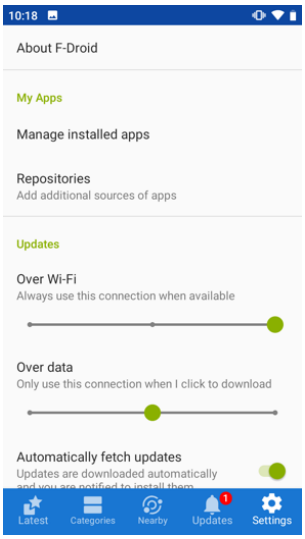


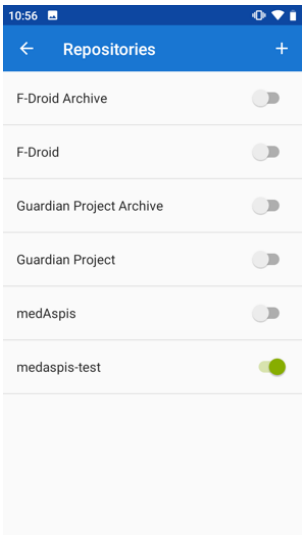
4.5.3 Installing test versions of the medAspis app

To use a test instance of the software, the existing app must be deleted and a test instance of the medAspis Connector⁺ app must be loaded from a test repository in F-Droid. The medAspis Connector⁺ app for the production system is in the „medAspis" repository, while the test application is in „medAspis test".

Start F-Droid from the handheld scanner's Android interface and go to Settings (bottom right in the F-Droid app). After clicking the „Repositories" button, a list of all active repositories appears. There will always be a „medAspis" repository, and the „medAspis staging F-Droid Repository" may also appear. This staging repository must be enabled, and the „medAspis" repository must be disabled.

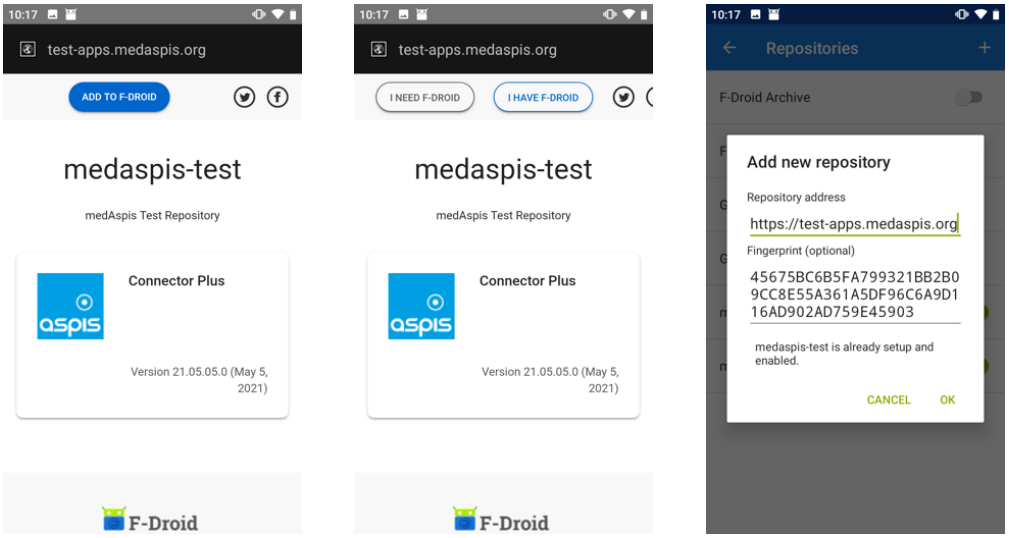






If the test repository has not yet been created, carry out the following steps in the medAspis Speed Scanner's browser:

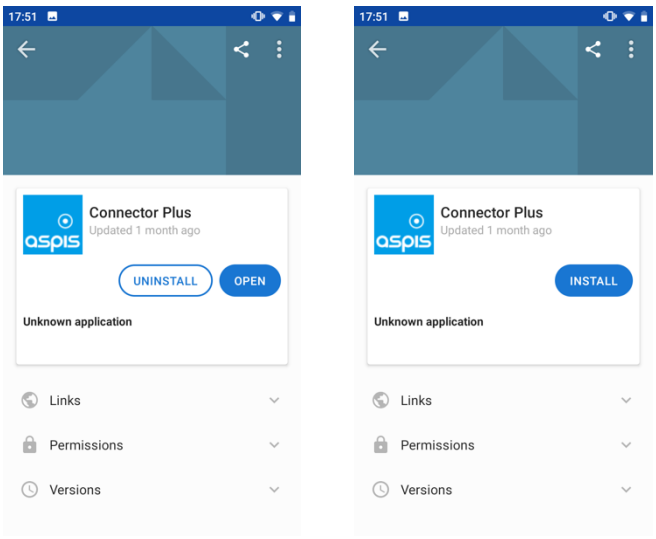
Open the medAspis Speed Scanner's browser and enter this URL: https://apps.staging.medAspis.org . A webpage from F-Droid appears. Please click the „ADD TO F-DROID“ button at the top of the window. Another window opens immediately. Now please press the „I HAVE F-DROID“ button. On the page that then appears, please confirm the displayed data with the OK button. The test repository is now set up in F-Droid.



Switch back to F-Droid, go to Settings and click on „Repositories“. You will now see all the data directories from which new applications can be loaded. To make sure that only the test application is loaded, please switch on the „medAspis test“ test repository and switch off the „medAspis“ production repository.

Switch back to the main F-Droid interface. Click „Latest“ in the menu at the bottom left. You may already see the medAspis app. If not, please use the search button at the bottom right. Type „medAspis“ into the search field. The app appears and can be tapped.

First, please press the UNINSTALL button to delete the existing application. Don't worry, the app will be loaded again in the next step. Please follow the further instructions of the uninstall process. As the next step, please follow the instructions for installing the new software.



The test software is now installed, and the medAspis Speed Scanner can be used in test mode. Please decide how you want to test the new app. A test panel is available for a complete test, but the app also works in the production environment.

You can reach the test panel at https://panel.staging.medAspis.org, and you will find the production environment as usual at https://panel.medAspis.org

You must activate the app in the respective desired environment. If your device is still connected to the system after installing the new app, please press the logo five times in a row in the app settings. This puts the device into registration mode, in which the device can be registered to a new environment.

Now start the panel in the production or test environment. If you use the test environment, you should be aware that packs scanned in this environment cannot later be transferred to the production environment. However, the test environment is also connected to your NMVS. If you want to avoid this, please ask your NMVO for a test environment and re-enter the access data.

Caution: it is important to follow the uninstallation and reinstallation routine, because the originally loaded production application must be deleted before the test application can be installed.

Caution: please do not forget to load a production app again after testing, in order to continue with production work. To do this, following the same procedure described above, switch off the „medAspis-test" test repository and switch on the „medAspis" production repository. Again, you must delete the current test app and reload the medAspis Connector+ app that is then offered. Make sure that the codes scanned with the new app appear in the production environment at https://panel.medAspis.com. If this is not the case, please repeat the installation process.

5 Typical applications of the Lean FMD system

This chapter outlines typical workflows using the Lean FMD system. If your workflow is not included in this list, please contact our support team. We can also assist you with your specific requirements.

5.1 Check or deactivate medicine packs using the Lean FMD system

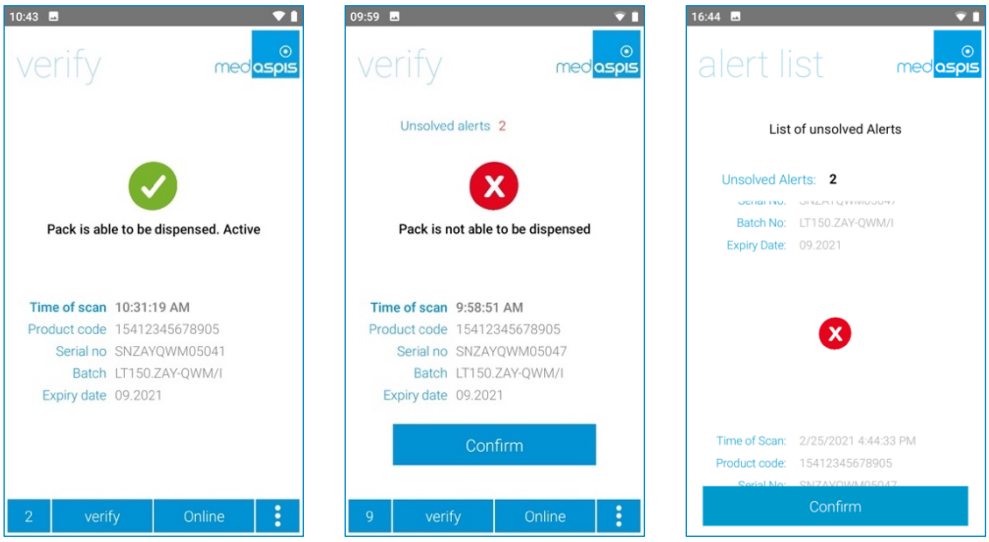
The Falsified Medicines Directive (FMD) requires the verification of medicinal product packs at various points along the pharmaceutical supply chain.

In the vast majority of cases, the likelihood of counterfeit medicines appearing within a company's own logistics operations can be virtually ruled out. medAspis Lean FMD has been developed precisely for these situations: to carry out all mandatory checks as quickly as possible, whilst remaining vigilant in case a counterfeit product does happen to turn up.

Typical activities include verification on goods receipt and deactivation at the wholesale stage in accordance with Article 23 of the Delegated Regulation. Both functions can be carried out quickly using the medAspis Speed Scanner. Verification is already set as the default in the FMD menu of the medAspis Speed Scanner. If deactivation is required, the relevant FMD function must be selected in the FMD menu of the medAspis Speed Scanner.

The result is usually positive: the pack is active or is deactivated using one of the deactivation functions. In both cases, a green tick appears on the display, and the medAspis Speed Scanner is immediately ready for the next scan.

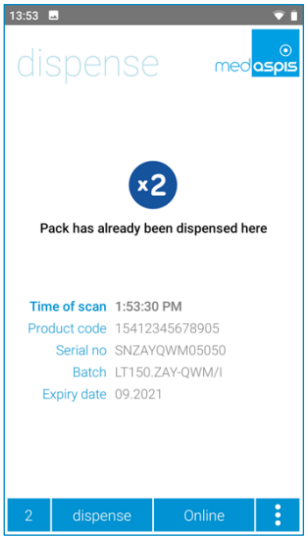
Thanks to Scan Accelerator technology, the scanning process is quick and easy. Should an error occur, a warning message appears; the scanner stops immediately and cannot be reactivated until a confirmation button has been pressed on the device's display. This process is also documented in the Scan History.



To prevent unnecessary error messages and the resulting interruptions to the workflow, the medAspis Speed Scanner automatically detects duplicate deactivations. Re-deactivating a pack that is already inactive results in an NMVS error. Such errors can occur frequently if a pack is accidentally scanned several times – whether due to carelessness or because the scanner captures 2D matrix codes so quickly that some packs are recorded multiple times even during the normal scanning process.

The medAspis system recognises multiple deactivations as duplicates and does not send them to the NMVS again. Instead, the result of the previous deactivation is displayed once more, but with the 'Double Dispense' symbol. The same entry is also displayed in the scan history, again with the 'Double Dispense' icon.

For a duplicate to be identified, the same pack must have been deactivated within the last 10 minutes using the same FMD command. When Alert Guard is enabled, this time period is extended to 2 hours.



In certain situations, the double deactivation filter is bypassed, allowing the operation to be repeated immediately. For example, if the NMVS system is temporarily unavailable. The double deactivation filter is also disabled for authentication operations (login, password entry, etc.).

All verified or deactivated packs appear as entries in the Control Panel's Scan History after a short time. In addition to the timestamp and pack data, the result of the NMVS check is also displayed. Packs that have passed the check are marked with a green tick, detected error messages with a red cross, and error confirmations with a blue information icon. The complete list of symbols is provided in the appendix.

In the Scan History, packs can be filtered and exported as required. The export always contains exactly those rows that were previously filtered in the Scan History. Some filters are already preset, but users are free to customise these filters to suit their own needs at any time.

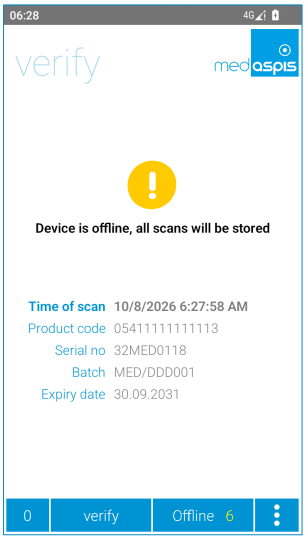
5.2 Working with packs that have been recorded offline

For the Lean FMD System to function without restriction, a permanent internet connection between the medAspis Speed Scanner and the Lean FMD System is required. As a rule, all scanned data records are transferred immediately from the scanner to the Lean FMD System, where further processing takes place.

Should the internet connection fail, this processing is disrupted. There are many reasons why a connection might be lost: the medAspis Speed Scanner or the Lean FMD System may not be functioning correctly, there may be a fault with the internet service provider, technical faults, or changes to the settings on the local Wi-Fi router.

Nevertheless, the medAspis Speed Scanner remains operational. Data is still captured, and work does not need to be interrupted. All codes recorded during the offline phase are saved within the medAspis Speed Scanner itself; under no circumstances will any data records be lost. The number of codes captured during this phase is displayed in yellow in the bottom bar.

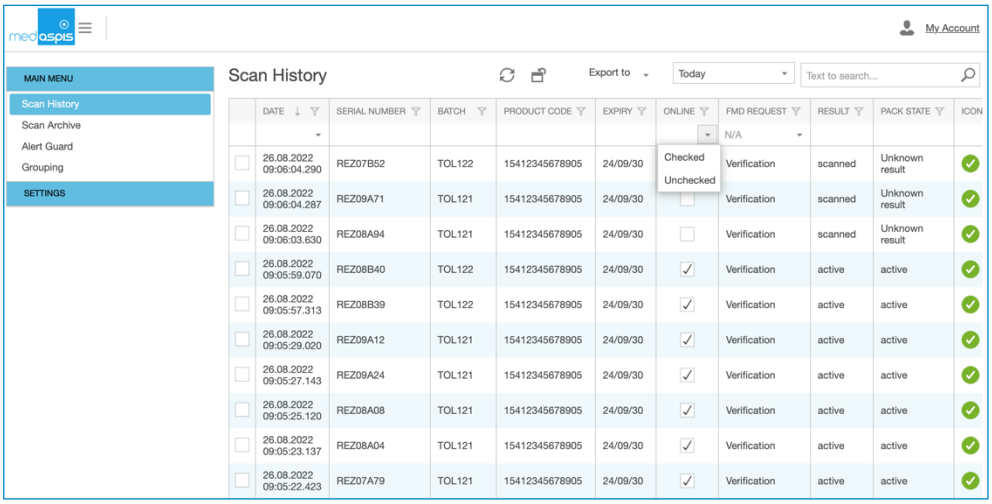
However, operational functionality is restricted. As there is no internet access, the data cannot be transferred to the Lean FMD System, direct processing by the relevant NMVS cannot take place, and no scan results can be displayed on the medAspis Speed Scanner's screen.



As soon as the internet connection is re-established, all data records captured and cached in the medAspis Speed Scanner will be transferred to the Lean FMD system. Depending on the volume of data, this may take a while.

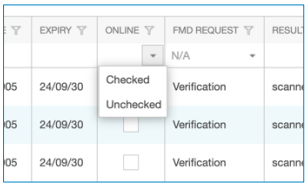
PLEASE NOTE: FMD operations recorded during the offline phase are NOT automatically executed by the Lean FMD system. As the Lean FMD system does not know how long the device was offline, and because a replacement scan may already have been carried out, it is up to the user to perform the FMD operations retrospectively.

Manual intervention is required to carry out the originally requested FMD operations. The data is displayed in the Scan History and marked as 'not online'. Using the filter function in the table column, all offline scans can be located and displayed immediately.

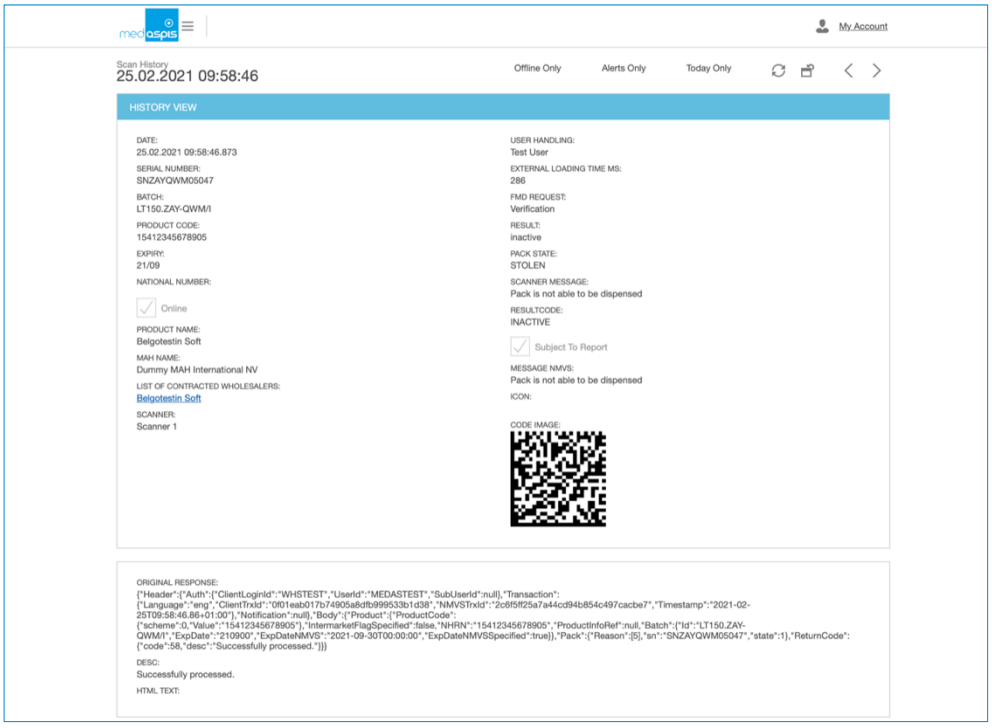


If you wish to send the entries marked as offline to the relevant NMVS, this must be done by scanning the pack codes again. However, the actual packs are no longer required for this. The 2D matrix codes on the medicine packs are reproduced in the Lean FMD system; these copies of the codes can be used for the repeat scan.

First, filter the packs marked as 'offline' in the Scan History using the column filter in the 'OFFLINE' column. Filter for 'Unchecked'. You will now only see the packs registered as 'offline' in the Scan History. You may need to set a date or time filter to ensure that only the desired offline scans are displayed in the Scan History.



Click on the first filtered row. The details for this scan will appear. Among other things, you will see a 2D matrix code. This code can be scanned using the medAspis Speed Scanner, just as if you were scanning it from the pack. Scan this code using the desired FMD operation. The scan will create a new entry in the scan history.



You can use the direction arrows in the top right-hand corner to jump straight to the detailed view of the next offline pack. These arrows remain active until you reach the last offline pack.

5.3 Working with groupings

Groupings are generally used to apply FMD operations to existing business processes. Either business processes such as deliveries are processed together, or packs are grouped into sales units such as cartons or pallets.

The groupings therefore reflect the respective structures of the customers' operational workflows and are used to simplify the work. However, they can also be used to communicate with external systems: external pack data can be imported via groupings, reports can be generated for groupings, and aggregation functions can be used to transfer groupings in bulk to other users.

A typical process flow for a pharmaceutical logistics provider is outlined below:
An order comprising 2,000 packs is to be deactivated. The order must be documented.

5.3.1 Order acceptance, start of process

The order is displayed on a screen in the company-wide WMS. A barcode appears alongside the order, showing the order number po7931465 and the number of products to be scanned.



The first step is to scan this barcode from the WMS screen using the medAspis Speed Scanner. The PO number now serves as the grouping name for the grouping to be processed. As the order is large and needs to be completed quickly, two operators work on the order simultaneously. The second operator also scans the same code from the WMS screen.

Both operators scan the packs for the order in the FMD operation VERIFY. The pack data from both medAspis Speed Scanners is stored in the grouping po7931465. The current count is synchronised across both medAspis Speed Scanners. Both operators are therefore aware of the current shared scanning progress.

As soon as the grouping reaches the target of 2,000 packs, both medAspis Speed Scanners stop. The laser scanners are automatically switched off; no further packs can be added to the grouping.

Both operators close the grouping po7931465 using the 'Complete' and 'Confirm' buttons.

Although the packs are to be deactivated according to the task specifications, in this first step they are initially only verified and deactivated at a later stage. This step-by-step approach offers operational advantages:

- It can never be ruled out that a scanner might accidentally read 2D matrix codes from packs that are not actually intended for processing. If these packs are then accidentally deactivated and nobody notices the error, they may no longer be fit for sale and will be excluded from further processing.
- The medAspis Speed Scanners can be configured so that only 'Verification' is available in the FMD menu.
- Verifications capture the 2D matrix code and store it for later operations in the Lean FMD system.
- Subsequent FMD operations can be carried out at any time and may fit better into the operational workflow. The later the deactivation takes place, the better one can respond to any changes to the order.

5.3.2 Further processing in the Control Panel

The grouping can now be found under this name in the Control Panel. The 'Grouping' menu item lists all groupings that have ever been created. As a rule, the most recent grouping appears at the top of the list.

Once the final packs have been entered and the process finalised by selecting 'COMPLETE' on the medAspis Speed Scanner, the grouping is assigned the status 'COMPLETED'. This status can be retrieved from the WMS via the medAspis API. The progress of the process can be automatically documented in the WMS.

The grouping is checked (number of packs, product purity, batch number if applicable) and can be deactivated with a single click (also via the WMS). A report can be generated immediately from the grouping view to send the order, including all serial numbers and FMD statuses, to the customer and the client. Reports are usually generated according to our customers' individual specifications.

5.4 Typical uses of aggregations

Aggregations are special groupings that are identified solely by aggregation codes. Various possible applications are conceivable:

5.4.1 Aggregation for the supply of hospitals

According to the European Commission, the supply of aggregated goods to hospitals is expressly permitted. medAspis has developed a system that enables deliveries to hospitals to be consolidated, and which automatically imports the

relevant codes into the hospitals' FMD systems at the same time as the medicine packs are dispatched. Hospitals are then no longer required to scan the packs themselves, but instead deactivate them on the basis of the electronically transmitted data records.

Wholesalers scan packs in advance for delivery to hospitals. All packs are scanned into a single aggregation. To do this, an aggregation label is affixed to the shipping carton and entered as the grouping name. Once all packs have been successfully scanned (verified), all pack data relating to the order is recorded within the aggregation.

All scan data is visible in the groupings in the Control Panel under the aggregation code. The status of this aggregation is then manually set to EXPORT.

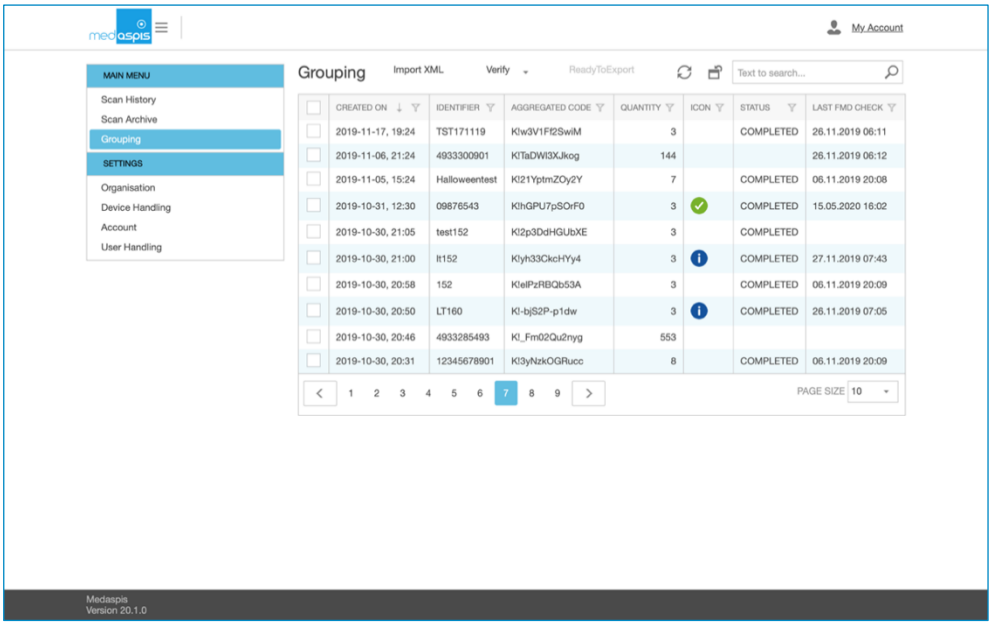
The hospital receives the aggregated products at goods-in. Instead of scanning them themselves, it is now sufficient to record the aggregation code on the outside of the box (manually or using a scanner). The aggregation is immediately transferred to the hospital's own stock and is available for further processing. In the Control Panel, all packs can be deactivated in one go without having to scan them again.

5.4.2 Sharing aggregated data

A cross-border delivery must always be verified by the recipient. Pack by pack. Even if the goods are coming from two different warehouses belonging to the same wholesaler. To simplify these intra-European deliveries, the serial numbers can be made available at the same time as the delivery. The recipient's warehouse can verify the goods received at the touch of a button and no longer needs to scan them pack by pack. FMD can be that simple.

5.5 Importing XML files

Product data can be imported into the medAspis Lean FMD system via an XML interface. If required, the XML import function can be enabled by medAspis support.



By clicking on the XML import button, an XML file can be imported into the system. The grouping name must be retained in the XML file, but can be changed manually at any time once the import has been successfully completed.

The pack data imported in this way can be processed further in any other grouping. FMD operations can be activated, and filter and reporting functions are available.

5.6 Warenbegleitende Datenlieferung

Warenbegleitende Datenlieferung ('Goods-accompanied data delivery') refers to a data format that is used only in Germany.

The medAspis system is designed to process data submissions accompanying goods. This German aggregation procedure is based on the XML standard. Wholesalers or manufacturers supply an encrypted XML file alongside the medicinal product packs.

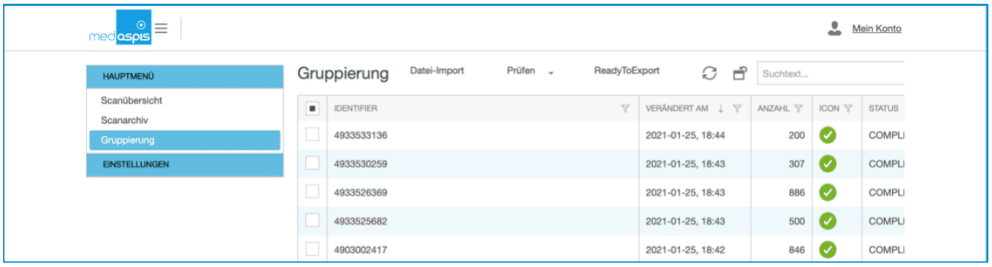
5.6.1 Day-to-day use of the WBDL portal

The medAspis WBDL Portal is used to upload and deactivate data transmissions accompanying goods in accordance with the standard set by the German Hospital Association.

5.6.2 Uploading new WBDL records

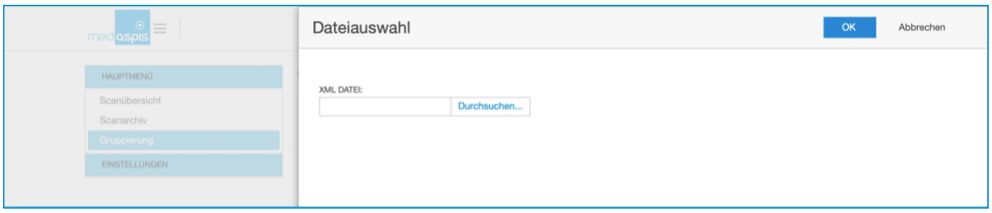
The data will be sent by email and will need to be unzipped. A password has been provided for this purpose. You can now easily upload the file containing the serial numbers to the WBDL portal.

Please go to the 'Grouping' menu option first.

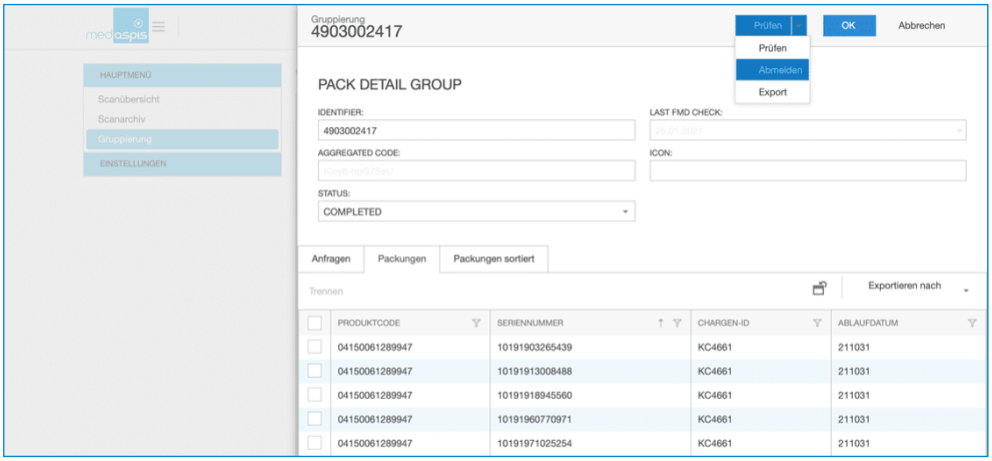


Please click the 'File Import' button at the top of the page. A new window will open immediately, allowing you to upload the file. Click the 'Browse' button and select the file from your computer's file system.

Complete the process by clicking OK.



The file will now be processed and all the packs that have been loaded will be displayed, showing the product number, serial number, expiry date and batch number. If you would prefer to process the file at a later date, simply press OK.

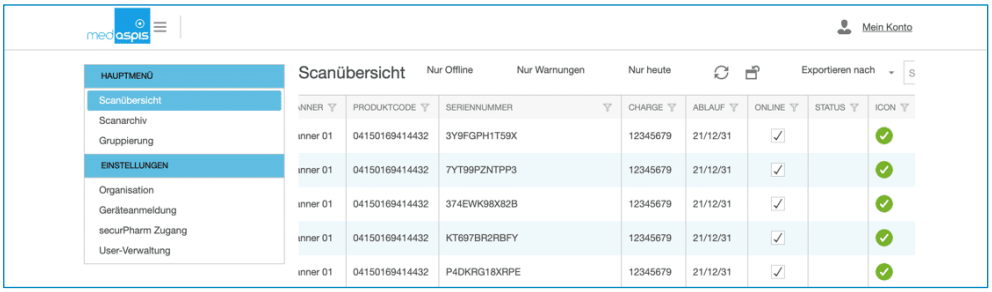


If you wish to deactivate the file packs immediately, select the 'Deactivate' option. All data records will now be deactivated of the securPharm account you have registered.

Clicking the OK button will take you back to the grouping view. Here you can see all the imported records. The rows marked with a green tick have already been deactivated.

Any errors are indicated by a red cross. Errors at this stage are very rare, as the data sets are supplied directly by the manufacturer. Should an error nevertheless be reported, please contact medAspis support. The error will certainly be identified quickly.

5.6.3 An overview of all scanned packs



Under the 'Scan Overview' menu item, you will find all the data records that have ever been scanned. Each one has been deactivated or verified by securPharm. You have a detailed overview of the time of deactivation and the status of the packs.

The results can be exported at any time, e.g. to Excel.

5.7 Reuse pack data multiple times, even without rescanning

Serial numbers for packs are often required on multiple instances. For example, entire cartons are scanned at goods-in for the required verification and then put into stock. These cartons are subsequently processed further – for instance, to be exported or, in the case of parallel importers, to be turned into new products for the domestic market. In such cases, the serial number must be recorded again.

However, this is not necessary with medAspis – here, it is sufficient to scan the pack data just once. The information already stored in the first step is simply reused to carry out the FMD operation in the second step..

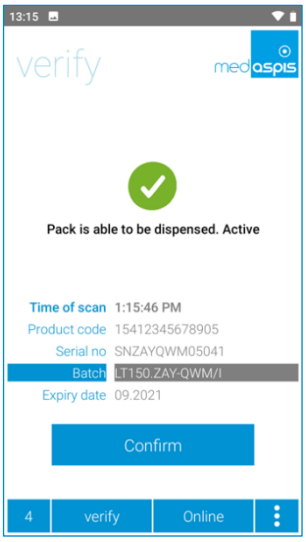
5.8 Identifying incorrect batches and products

In many stages of production and distribution, strict processing by product type is mandatory. For parallel trade in particular, it is a priority to ensure that packs with incorrect batch numbers or even incorrect product codes do not accidentally find their way into otherwise homogeneous consignments.

The medAspis Batch Control module prevents the unwanted scanning of incorrect packs. Once Batch Control is activated, the user is warned as soon as an incorrect batch or pack is scanned. Incorrect batches are not incorporated into the current production run.

The Batch Control option can be enabled in the settings of the medAspis Speed Scanner. When this function is enabled, the medAspis Speed Scanner issues a warning if a batch or product code is scanned that differs from a reference pack.

The reference pack is determined by the first scan following a reset of the counter, displayed in the bottom left-hand corner of the medAspis Speed Scanner screen..



6 Appendix

6.1 Appendix: Icons

The symbols used in the system follow a colour scheme:

6.1.1 NMVS colours:

The icons for the NMVS responses are displayed in the familiar traffic light colours: green, amber and red.

OK 

Warning 

Error/Alert 

6.1.2 System colours:

Other icons providing additional system information for the medAspis system are shown in blue.

Scanned only 

Information 

Double Dispensing 

Waiting for bulk upload 

6.2 Appendix: XML format for importing pack data

XML files in the following sample format can be imported.

```
<Shipment snr="grouping">
    <Content dfi="GS1">
        <GTIN>05060540780010</GTIN>
        <SN>2214300000000709</SN>
        <LOT>22143</LOT>
        <EXP>250331</EXP>
    </Content>
    <Content dfi="GS1">
        <GTIN>05060540780010</GTIN>
        <SN>2214300000020612</SN>
        <LOT>22143</LOT>
        <EXP>250331</EXP>
    </Content>
</Shipment>
```