

Guidance document
draOnline help for the MD publication service

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1 Introduction

This document is designed to help people use the Swissmedic website with the list of Field Safety Corrective Actions. It aims to show what information is published, how it is published and the available search options.

The document also answers those questions that are frequently asked by visitors to this site.

2 Explanation of columns

Each Field Safety Corrective Action reported to Swissmedic is also published on the Swissmedic website with the Field Safety Notice. Each individual Field Safety Corrective Action is managed by Swissmedic as a case with its own case number, which is made up of the date of the report and a sequential number for this day: Vk_YYYYMMDD_xx

Date	Manufacturer	Trade name	Product description	Information	Swissmedic reference
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Figure 1: Presentation of the displayed information

Date:	Date of publication
Manufacturer:	Name of the manufacturer of the medical device
Trade name:	Information about the medical device concerned (name(s) and, if applicable: model number(s) and or catalogue number(s), lot number(s), serial number(s), software version(s))
Description:	Brief description of the medical device concerned: MD = classical medical device or active implantable medical device, IVD = in-vitro diagnostic device
Information:	linked letters to customers stating the language (DE = German, FR = French, IT = Italian, EN = English) and versions
Swissmedic reference:	Swissmedic reference number

3 Status of publications


The status of a publication specifies whether a new publication or an update to a publication is involved. A further distinction can be made by establishing whether corrections or additional versions of letters to customers in other languages were involved.

3.1 Publication: First publication

A case was published for the first time. This case receives a “first publication” date, which you can find in the “Date” column.

3.2 Publication: First publication with additional languages


The customer letter for a newly published case was published on the site in one or more additional languages.

This case receives a status date (date of publication of further languages), which you can find in the “Date” column with the addition “Updated dd.mm.yyyy”, together with the message “added new language” by hovering over the  icon with the mouse. The first publication date never changes.

3.3 Publication: Update


This refers to an update concerning a previously published case received by Swissmedic from the manufacturer, its representative or distributor (content-related correction, e.g. additional Field Safety Notices, recall of other affected lots, further information on the follow-up treatment of a patient with an affected implant). This is published as an “Update” to the first publication.

This case receives a status date (date of the update), which you can find in the “Date” column with the addition “Updated dd.mm.yyyy”. The first publication date never changes.

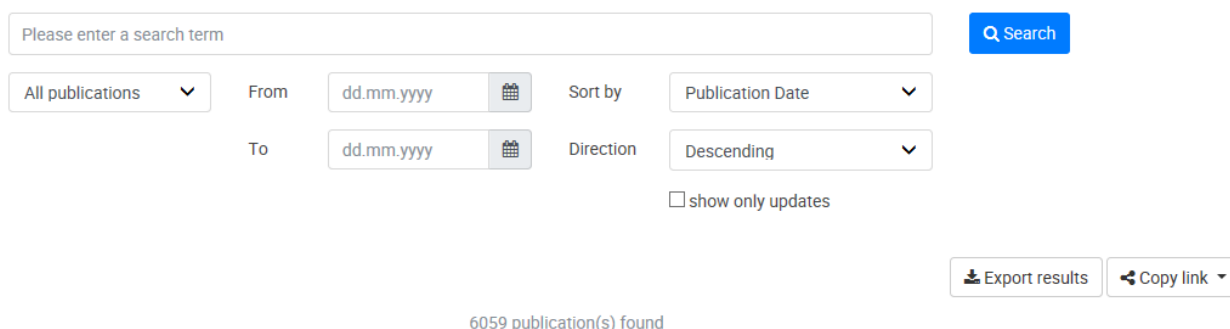
You can obtain a brief summary of the reason for the update by hovering with the mouse over the  icon.

3.4 Publication: Update with additional languages

The customer letter for an updated case was published on the site in one or more additional languages.

This case receives a status date (date of publication of updated customer letter in additional languages), which you can find in the “Date” column with the addition “Updated dd.mm.yyyy”. The first publication date never changes. You can obtain a brief summary of the reason for the update by hovering with the mouse over the  icon.

4 Search functions



Please enter a search term Search

All publications From dd.mm.yyyy Sort by Publication Date

To dd.mm.yyyy Direction Descending

show only updates

Export results Copy link

6059 publication(s) found

Figure 2: Presentation of the search functions

4.1 Search: Free text

You can search for a word or group of words. The displayed results include all the search hits within all fields and all machine-readable customer letters in pdf format.

4.2 Search: Last 7 days

The search phrase “Last 7 days” shows all search hits for those publications that were newly published or updated within the last 7 days (counting back from today).

4.3 Search: Last month

The search phrase “Last month” shows all search hits for those publications that were newly published or updated within the last month (counting back from today).

4.4 Search: Last year

The search phrase “Last year” shows all search hits for those publications that were newly published or updated within the last year (counting back from today).

4.5 Search: Selecting a defined period

You can specify your own defined period by entering the start and end dates in the search. To do this, use the “User-defined” filter.

4.6 Search: Only show updates

Searching for an “Update” by selecting “Only show updates” shows all cases that have been updated. You can also limit the search for updates with the other search functions.

4.7 Search operators

If your search produces either no or too many results, you may be able to refine it by using search operators.

4.7.1 * at the end of a word

Simple searches only produce results that contain the actual term you are searching for. If you want to include results where the term is part of a word, add an * operator to the end of the term. For example, searching for hip* will produce results containing hips or hipbone.

4.7.2 + means “and” (default when running searches)

If you search for two terms, they are linked by an “and” operator by default, and you only see results that contain both words. Using a “+” operator has the same effect.

4.7.3 | means “or”

If you enter two terms, but only want to see results that contain either word but not both, you should use the “|” or “or” operator.

4.7.4 - excludes terms

If your search produces too many results, you can exclude individual terms by inserting an “-” operator in front of the terms you want to exclude (e.g. - Ltd only shows results that do not contain the word “Ltd”).

4.7.5 "searches for exact phrases

If you enter two or more words, the program will by default search for all those words, but without taking account of their position relative to each other. If you want to search for the terms as part of an exact phrase, place "before the first and after the last term.

4.8 Displaying search results

4.8.1 Sort by and Direction


You can decide which order you want search results to be displayed in using the “Sort by” and “Direction” options.

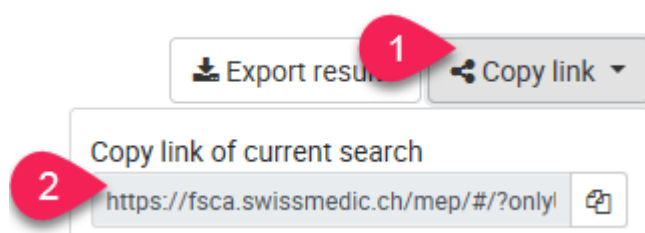
Sort by: You can choose to sort by either publication date or Swissmedic reference number.

Direction: You can choose between ascending and descending order.

5 Copying links

You have the option of storing or sharing searches. Use the search filters to obtain a list of results that matches your needs. To save or share this list, click first on “Copy link”. A window with a link to the

current search will open. Click on the  symbol to copy the link. You can now save the link for subsequent use or share it with someone (e.g. by e-mail).



6 Exporting results

You can use the export function to produce a list (in the form of an Excel table) of all the cases that you have found in a search.

6.1 Exporting results: Procedure

1. Perform the desired search, e.g. for a company or product name or for a limited period.
2. Click the “Export results” field
3. A csv file with all the search results is generated.
4. Select a storage location for this csv file.
5. You can now open the csv file and edit, sort and use the results as you like.

6.2 Converting a CSV file into an Excel table: brief explanation

How can I create a sortable Excel table from the csv file?

6.2.1 Option 1

1. Open the csv file in Excel by right-clicking the file, selecting “Open with” and choosing Excel.
2. Select the first column (A).
3. Under the “Data” tab click the “Text to Columns” function.
4. Select “Delimited” as the file type, “Comma” as the delimiter, “General” as the column data format and finish the conversion.
5. You will now have a sortable Excel table with the following columns:
 - a) the top row shows the link that represents your completed search
 The following columns are displayed below the top row:
 - b) swissmedicRef: Swissmedic reference number
 - c) publicationDate: Date of first publication
 - d) statusDate: If an update was published: Date of this update
 - e) reason: Description of the reason for an update
 - f) manufacturer: Name of the manufacturer
 - g) tradename: Name of the medical device/medical devices concerned
 - h) description: Description of the medical device/medical devices concerned (MD = classical medical device or active implantable medical device, IVD = in-vitro diagnostic device)
 - i) model: Model number and/or catalogue number(s) of the medical device / medical devices concerned
 - j) lot: Lot number(s) of the medical device/medical devices concerned
 - k) sn: Serial number(s) of the medical device/medical devices concerned
 - l) softwareVersion: Software version of the medical device/medical devices concerned
 - m) directLink: direct link to the case
6. Click “File” and “Save as”. Choose the file location and “xls” file type before saving, otherwise the formatting will be lost.

6.2.2 Option 2:

1. Open an empty Excel sheet.
2. Click “File”, “Open” and locate the csv file. Make sure the “All files” option is activated and select the csv file.
3. The wizard will open automatically.
4. Select “Delimited” as the file type, “Comma” as the delimiter, “General” as the column data format and finish the conversion.
5. You will now have a sortable Excel table with the following columns:
 - a) the top row shows the link that represents your completed search
 The following columns are displayed below the top row:
 - b) swissmedicRef: Swissmedic reference number
 - c) publicationDate: Date of first publication
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 - l) softwareVersion: Software version of the medical device/medical devices concerned
 - m) directLink: direct link to the case
 - a) Click “File” and “Save as”. Choose the file location and “xls” file type before saving, otherwise the formatting will be lost.

7 FAQ

Frequently asked questions are answered in this section

7.1 Why is the description of the devices concerned only available in English?

The devices are described using the nomenclatures that are applicable worldwide (GMDN: Global Medical Device Nomenclature, EDMA: European Diagnostic Manufacturers Association (=Global InVitro Diagnostic (GIVD) Classification), UMDNS: Universal Medical Device Nomenclature System or EMDN: European Medical Device Nomenclature). The device descriptions are made available and regularly updated in English by the relevant agencies. It is not possible for Swissmedic to have these nomenclatures regularly translated into all national languages.

7.2 Why are the letters to customers not published in all languages?

Swissmedic usually publishes all the customer letters provided by the manufacturer, its representative or distributor. If not all linguistic regions in Switzerland are affected by a Field Safety Corrective Action (because the device is not available on the market there), then no customer letter will exist in the respective language.

Sometimes Swissmedic does not make available all the language versions of a customer letter on time. In this case, Swissmedic publishes all the available customer letters immediately and the subsequently received translation at this later date.

For some Field Safety Corrective Actions the customer letter is only made available in English, but this only applies if the device is used by professional users, and these users have declared that a translation of the customer letter into one of Switzerland's national languages is not necessary.

7.3 Why is Swissmedic publishing the letter only now even though I received the letter 2 weeks ago and dated accordingly?

Swissmedic always publishes a case when it has received at least one customer letter from the company. After it is reported to Swissmedic, the case is processed by a scientific officer and published within two weeks of the receipt of the report. This is why you received the customer letter before it was published. Further delays can arise if a company is late in submitting a report to Swissmedic.

7.4 Why does the web page with lot/serial numbers often refer to the customer letter?

If the list of affected models, serial numbers or lot numbers is too long, listing them on the web page becomes too confusing. Swissmedic therefore reserves the right to refer to the customer letter.

Change history

Version	Change	sig
1.1	New layout, no content adjustments to the previous version	tsj
1.0	Doc newly created owing to revision of MD regulatory provisions; old doc ID: MU510_00_010e_MB	dra