USERGUIDE FOR THE FAMHP PLATFORM

COMPANIES BASED OUTSIDE BELGIUM

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1   INTRODUCTION

All economic actors that operate in the medical devices sector on the Belgian territory are invited to register on the Federal Agency for Medicines and Health Products' (FAMHP) web portal.
This guide is intended for companies located outside of Belgium but within the European Economic Area or in the European Union Customs Union.

The user guide contains the several steps:
- Entry of enterprise data;
- verification and validation of these data by the FAMHP's internal departments;
- configuration of access for the Chief Access Manager (CAM);
- configuration of CSAM platform;
- configuration of access to the platform using KeyCloak (only non-Belgian users).

The steps to take in order to register and log in to the FAMHP platform are summarised in the following diagram:
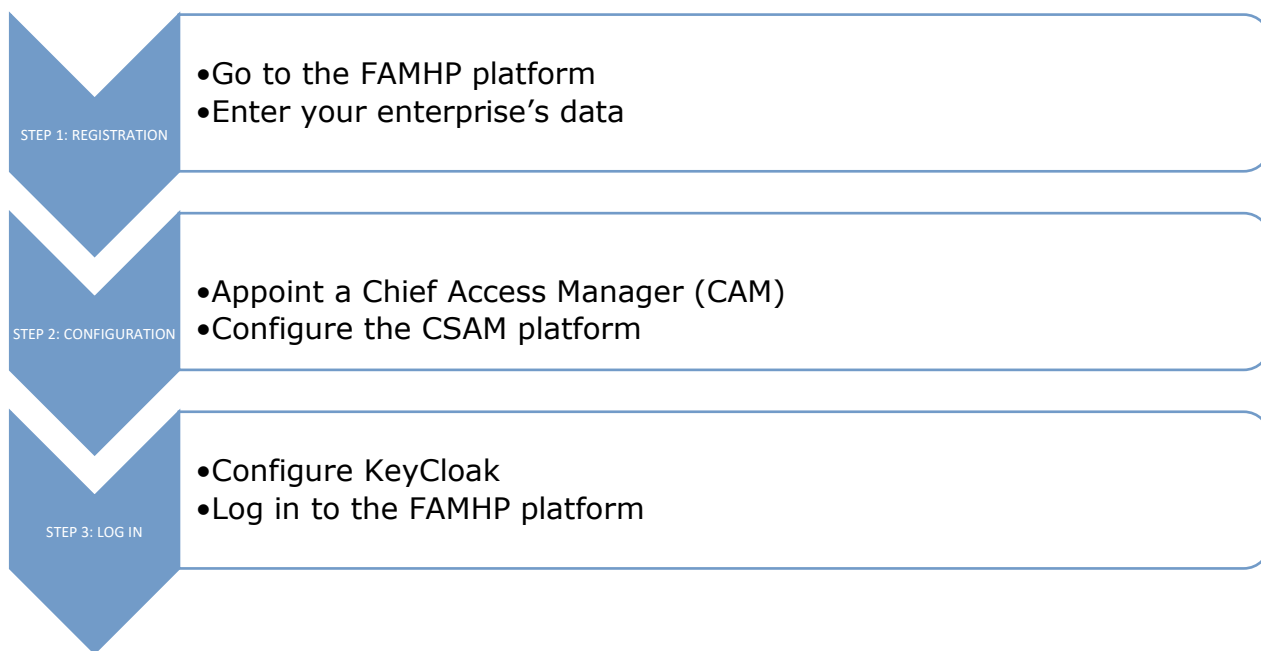
STEP 1: REGISTRATION
- Go to the FAMHP platform
- Enter your enterprise's data

STEP 2: CONFIGURATION
- Appoint a Chief Access Manager (CAM)
- Configure the CSAM platform

STEP 3: LOG IN
- Configure KeyCloak
- Log in to the FAMHP platform

Figure 1

2 REGISTER

Click on the "Register" link that appears on the public page of the FAMHP portal(
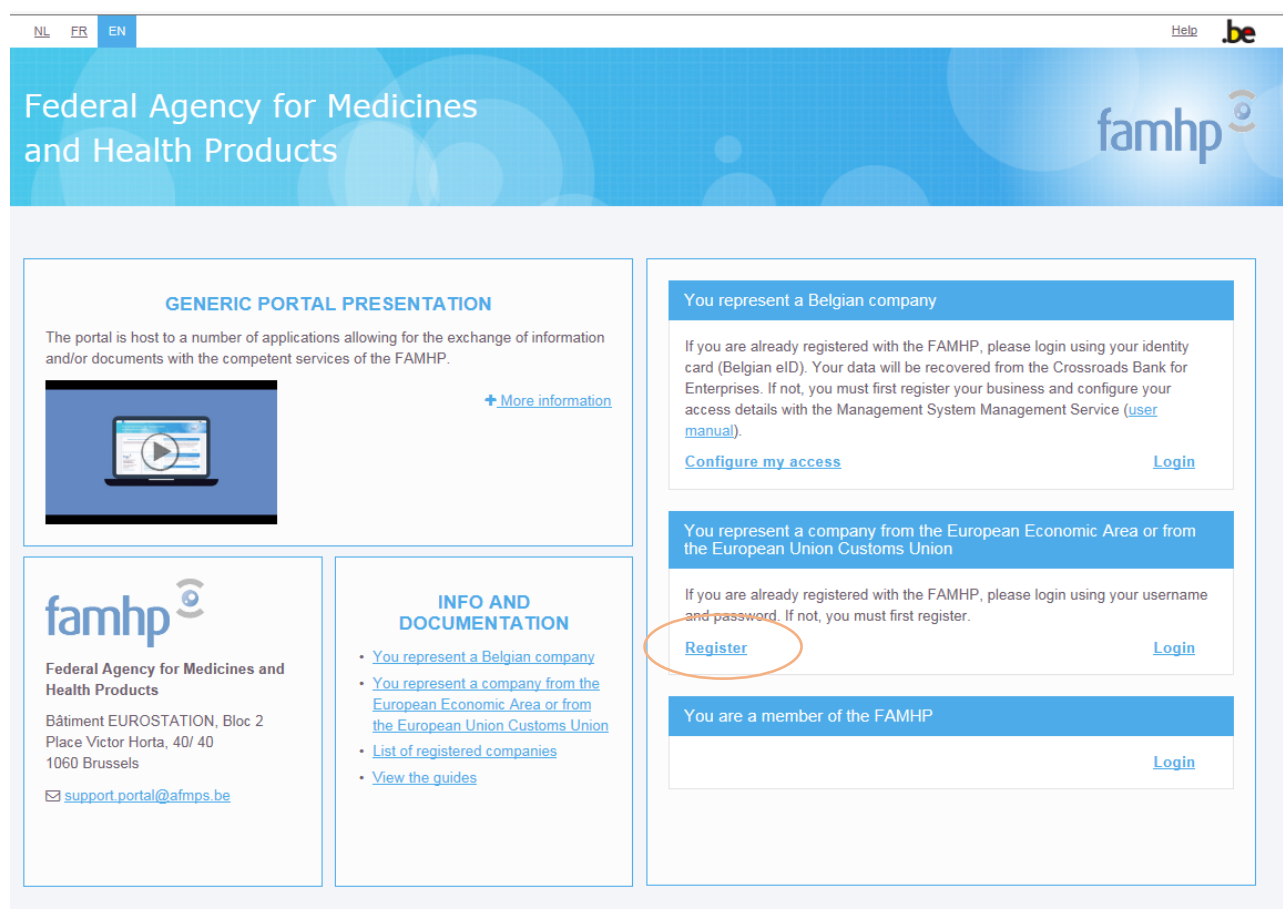
Figure 2).

Figure 2

2.1 VERIFICATION OF THE ENTERPRISE NUMBER

To register at the FAMHP, the enterprise must have an acknowledged enterprise identification number that can be found in the VIES directory or in the Crossroads Bank for Enterprises (CBE).

If your enterprise is located **outside Europe**, the application will ask you to enter your enterprise number as it appears in the CBE. If you do not have a CBE enterprise number, please contact the FAMHP to register with the BCE.

Figure 3

For companies from the European Economic Area or from the European Union Customs Union the application will ask you to enter or select the following information (figure 4):

- The country in which the enterprise is based (select from the drop down menu).
- The Crossroads Bank for Enterprises (CBE) number, if the enterprise already obtained a registration in this database.
  It is important to provide this number to prevent having to re-enter data already been sent to the authorities, thereby prolonging the data validation procedure.
  Otherwise, please indicate that you don't have a CBE number.
  If you are unsure whether or not your enterprise is registered at the CBE, you can run a search on the CBE website.
- The enterprise's VAT number (intercommunity VAT number).

Once you have entered all these data, click on the "Identification of the enterprise" button.

The system will check the validity of the enterprise number against the European database, the VIES (VAT Information Exchange System).

Registering a foreign enterprise:

Identification of the enterprise	
	* Mandatory
Please select the country where the company's head office is located	Spain ▼
If you already have an enterprise number, it is important to communicate this to us in order to avoid that you have to re-enter data that has already been provided to the authorities. Are you not sure whether you are already known or what your enterprise number is? You can run a search at this site.	
Are you registered at the CBE ? ⦿ Yes ○ No	
Enterprise number (CBE)	
VAT number ES _____ *	Identification of the enterprise

Figure 4

This verification does not apply to Swiss companies.

For some enterprises in the United Kingdom and Ireland that do not have a VAT number, you only need to select the country in which the company's headquarters is located, then click on "identify a company without VAT number" (Figure 5).

Registering a foreign enterprise:

Identification of the enterprise	
	* Mandatory
Please select the country where the company's head office is located	United Kingdom ▼
If you already have an enterprise number, it is important to communicate this to us in order to avoid that you have to re-enter data that has already been provided to the authorities. Are you not sure whether you are already known or what your enterprise number is? You can run a search at this site.	
Are you registered at the CBE ? ⦿ Yes ○ No	
Enterprise number (CBE)	
VAT number GB _____ identify a company without VAT number.	Identification of the enterprise

Figure 5

If the VAT number is refused, please consult the site of the European Commission.

Enter your enterprise data

Once your enterprise number has been verified, the next step consists of entering your enterprise data.
To do so, you will be asked to supply at least the following information:

- The enterprise data:
  - Enter the commercial name of your enterprise;
  - Select the language you wish to use for communication between the enterprise and the FAMHP. The FAMHP only provides communication in the following languages: French, Dutch and English;
  - Enter the enterprise's legal status by uploading official proof from the register of trade and commerce and/or an extract from the chamber of commerce.
    Make sure it states the commercial name of the enterprise, as well as the names of the administrators. If this is not the case, your request will be declined.
    You can upload only one single file, but you are allowed to merge first several files into one file and upload the resulting file.
  - Enter the address of the registered office.

- Enter your enterprise's business sites[1];
- Provide the identity of the enterprise's legal representative(s):
  - If the legal person is already registered at the Belgian Social Security, enter this person's NISS number (Social Security unique identification number or Belgian national number, in French: NISS) to avoid having to re-enter their information;
  - Name and first name (the first letter of the first name must be written in capitals);
  - Sex;
  - Date of birth;
  - Country of birth;
  - Email address of the legal representative(s). Each user will have to provide their own email address.
- Provide also at least one contactperson

Once the enterprise information has been entered, the enterprise's legal manager and the contact(s) will receive an email containing all the information explained in the following chapter.
Lease check the spam filter of the company: all emails coming from "fagg-afmps.be", "fagg.be" and "afmps.be" should be allowed.

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[1] The headquarter office

3 CONFIGURE CSAM

3.1 APPOINT A CHIEF ACCESS MANAGER (CAM)

Before using the FAMHP platform, the enterprise's legal representative is asked to a appoint a Chief Access Manager (CAM[2]).

The system has been designed so that the CAM is also the Access Manager[3] (AM) for each group of applications (domain).

The Chief Access Manager, is the person responsible for managing the enterprise's access to the Belgian federal government and is the primary point of contact for issues regarding Social Security and other institutions. This person is responsible for managing the different qualities related to their professional activities and has access to a range of information.

At any time the CAM can delegate access management by appointing one or more AMs or Co-Enterprise Access Managers (Co-CAM) per application group.

To appoint a CAM, we invite you to log in to CSAM

A. Belgian citizens:
   - follow the steps outlined in point II of the CSAM manual (in French) or Anteilung (in German) or :
   - "Management of Access Managers", "Appointing a Chief Access Manager", "Appointing a Chief Access Manager"
   - "Verwaltung der Zugangsverwalter", "Einen Hauptzugangsverwalter einrichten" , "Einen Hauptzugangsverwalter einrichten.

B. Non-Belgian citizens: you need the NISS number, also called national number which you received by email
   - follow the steps outlined in point II of the CSAM manual (in French) or Anteilung (in German) or :
   - "Management of Access Managers", "Appointing a Chief Access Manager", exception procedure.
   - "Verwaltung der Zugangsverwalter", "Einen Hauptzugangsverwalter einrichten" – Ausnahmeverfahren.

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[2] The Chief Access Manager must be a member of staff or a legal representative of the company as mentioned in the uploaded document.
[3] .

3.2 CONFIGURE CSAM

3.2.1 ACTIVATE THE ENTERPRISE'S QUALITIES AND APPOINT AN ACCESS MANAGER

The PAM (see point 3.1) is responsible for activating the enterprise's qualities. They will receive the login and password to configure the National Office of Social Security's (ONSS) platform if they are not a Belgian citizen or don't have an eID.

To activate the enterprise's quality:
1. Log in to the social security (only in French, Dutch or German) portal;
2. Belgian users: click the red 'se connecter' or eID or Itsme
3. Non-Belgian users: click the blue 'se connecter' (figure 6);
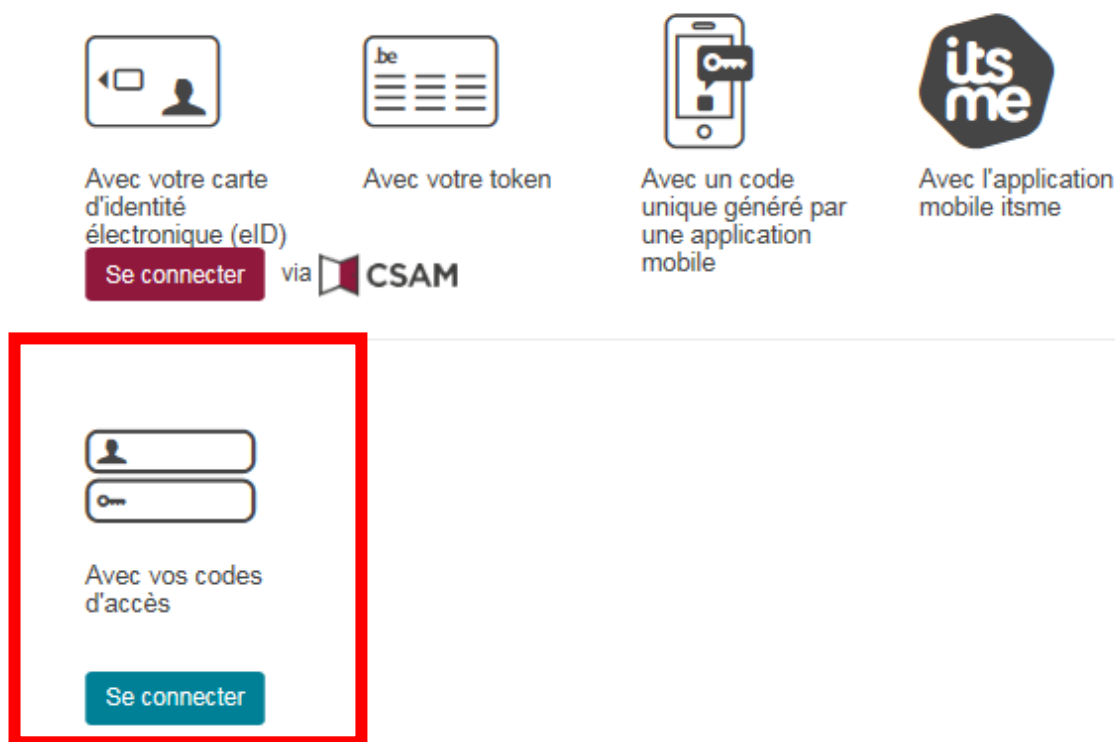
Figure 6

4 . Non-Belgians : 'Continuer à utiliser l'option moins sûre'

Use the login and password sent by CSAM (or Eranova) (Figure 7);
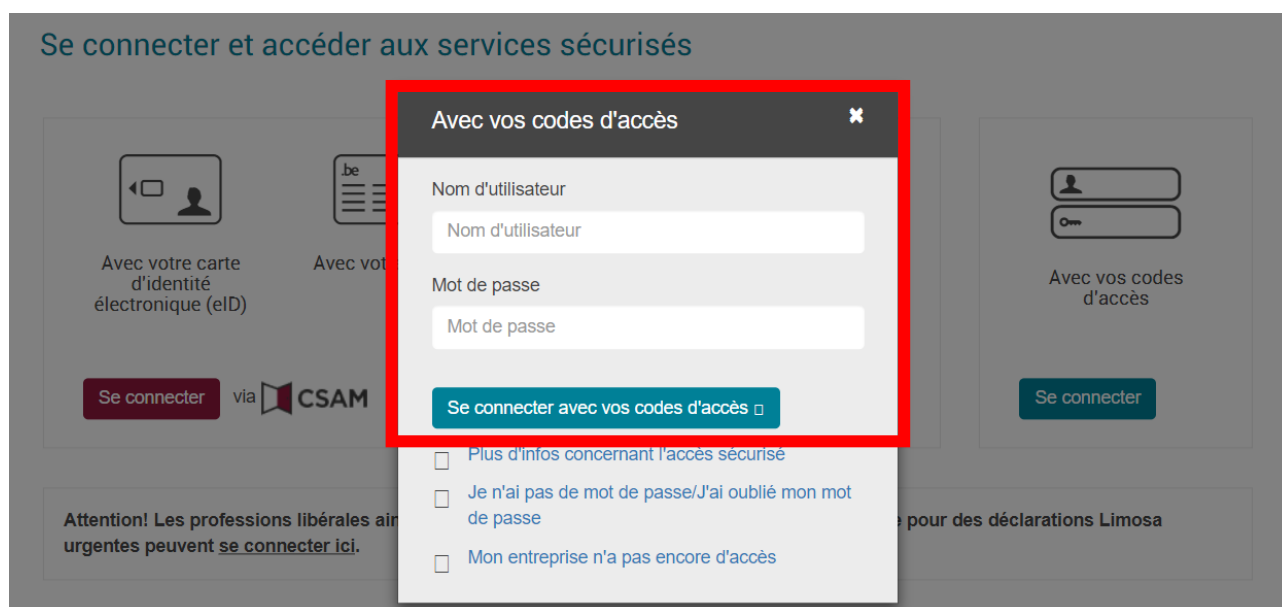
Figure 7

4. Click "Healthcare - Manager" ("Soins de santé - Gestionnaire") or "Healthcare actor" ("Acteur des soins de santé") to select the profile with which you need to log in to the Social Security portal

Portail de la Sécurité Sociale

Sous quelle qualité voulez-vous vous authentifier?

| EMPLOYEUR | ACTEUR DES SOINS DE SANTÉ |

5. Select the enterprise you would like to work with within this application;

6. If the enterprise's quality (institute in the healthcare domain) ("**Institution liée au domaine de santé**") has already been activated, the information will appear on the screen (figure 9);

Choisissez l'entreprise ou l'organisation pour laquelle vous souhaitez travailler au sein de cette application

Plastique Fantastique; Numéro d'entreprise: 1000.439.093 ▼

Cliquez sur le lien souhaité

Dénomination: Plastique Fantastique; Numéro d'entreprise: 1000.439.093 (Responsable Accès Entité)
- Qualité: Affaires intérieures; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Affaires étrangères; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Chaîne Alimentaire; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Economie; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Emploi; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Entreprise sans personnel; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Environnement; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Finances; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Institution liée au domaine de la santé; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Justice; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Logement; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Marchés publics; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Mobilité (transport, infrastructure, télécommunication); Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Planification; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Services généraux; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)
- Qualité: Soins de santé; Numéro d'entreprise: 1000.439.093 (Gestionnaire Local)

Figure 10

7. If you don't see this quality: double click the title "Dénomination .... (**Responsable Accès Entité**)" (Name .... (Entity Access Manager))
8. Select in the drop down under the list "**Institution liée au domaine de la santé** "(institute in the healthcare domain) (Figure 8);
9. Click "Suivant" (Next).

Figure 8

10. Add an email address for the quality. This address should preferably be shared by all of the quality's users.

To appoint the AM or the Local Manager[4]

1. Tick (Figure 9):
   a. Either you want to manage the quality by myself: "Je desire assurer moi-même la gestion de la qualité". The CAM will be appointed Access Manager (AM) of the quality and will be able to grant access for users.
   b. Or you would like to appoint a Local Manager[5] to manage the quality": "Je veux designer un Gestionnaire local pour gérer la qualité". Then the CAM may appoint another person to manage the quality and user access. To appoint another person, the CAM must have the new AM's NISS number (national number).

4

Figure 9

2. If you select the option "I want to manage the quality myself";
   a. Click "Suivant" (Next),
   b. Confirm the data you have entered by clicking "Confirmer" (Figure 11).

Figure 10

3. If you have selected the option « Je veux désigner un Gestionnaire local [6] pour gérer la qualité » (I would like to appoint a Local Manager[7] to manage the quality):
   a. Select the « Ajouter un Co-gestionnaire » (Add a Co-Manager) function (Figure 11);
   b. Enter the Co-Manager's NISS number;
   c. Click "Suivant" (Next);
   d. At this stage, you can
      - add a new user,
      - change the AM,
      - delete a user,
      - block or unblock a user.

Figure 11

3.2.2 APPOINT USERS

1. Click the "Home" menu located at the top-right of the screen (Figure 12).

Figure 12

2. Select the « Institution liée au domaine de la santé ; ... » (Institute in the healthcare domain; …" quality)(Figure 14**Fout! Verwijzingsbron niet gevonden.**).

Figure 13

3. Click the « Utilisateurs » (Users) menu (Figure 14).

4. Select « Ajouter un utilisateur » (Add a user) (Figure 15).
5. Enter the user's NISS number (Figure 15).
6. Click "Suivant" (Next).

7. Add the user's information (title, language and email address) (Figure 16).
8. Select apps (Figure 16):
   a. Autocontrôle,
   b. Contributions
   c. source Authentique des représentants autorisés (Authentic source for authorised representatives),
   d. portail MEDSEIP (MEDSEIP portal),
   e. source Authentique des acteurs (AFMPS) (Authentic source for actors (FAMHP)),
   f. source authentique des activités et classes (Authentic source for activities and classes),
   g. source authentique des certificats à l'exportation (Authentic source for export certificates),
   h. source authentique des dispositifs médicaux (Authentic source for medical devices);
9. Click "Enregistrer" (Save) (figure 19).

Figure 16

10. Check the data and click "Confirmer" (Confirm) (Figure 17).

Figure 17

3.2.3 ADD SUPPLEMENTANY NON-BELGIAN USERS

All non-Belgian contacts declared when applying for registration got automatically a NISS number and an account for the FAMHP portal. This information was sent to them via an automatic mail.

If extra non-Belgian users should be defined, they first of all should be added by a collegue in the portal as an extra contact in the tile 'My enterprise'. If no NISS number is entered, the system pops up and asks the extra informatie required to create a NISS number. After confirmation of the new data (button right

bottom of the screen) the NISS number and account will be created automatically, the NISS number and temporary login will be sent to that contact.

This person should then also be declared as a user or co-manager in the site of the social security (chapter 3.3.2).

4.1 NON-BELGIAN USERS: CONFIGURING KEYCLOAK (THE "TIME-BASED-ONE-TIME-PASSWORD" TOTP SYSTEM)

The FAMHP platform allows enterprises in the European Economic Area or the European Union Customs Union to log in using the TOTP ("Time-based-One-Time-Password") system, a system that issues a new password every 30 seconds via smartphone.
The legal representatives and other contacts defining in the request for registration (chapter 2) received an email containing:
- their login names (=NISS number);
- their temporary passwords, which will be changed when they log in for the first time.

To log in to the platform, you must first download a one-time password generator on your smartphone, available from the various app marketplaces: Apple Store, Windows Store or Android Store.

Login applications, such as Google Authenticator or Microsoft Authenticator, can **be installed** and used for free on a PC or smartphone. They respect the TOTP protocol.

In this user guide, we use "Google Authenticator" as an example. To configure this app, please consult the Google manual.

To configure the KeyCloak system:
1. Log in to the FAMHP portal ;
2. Click "Login" (figure 19)

Figure 18

3. Click " " ;
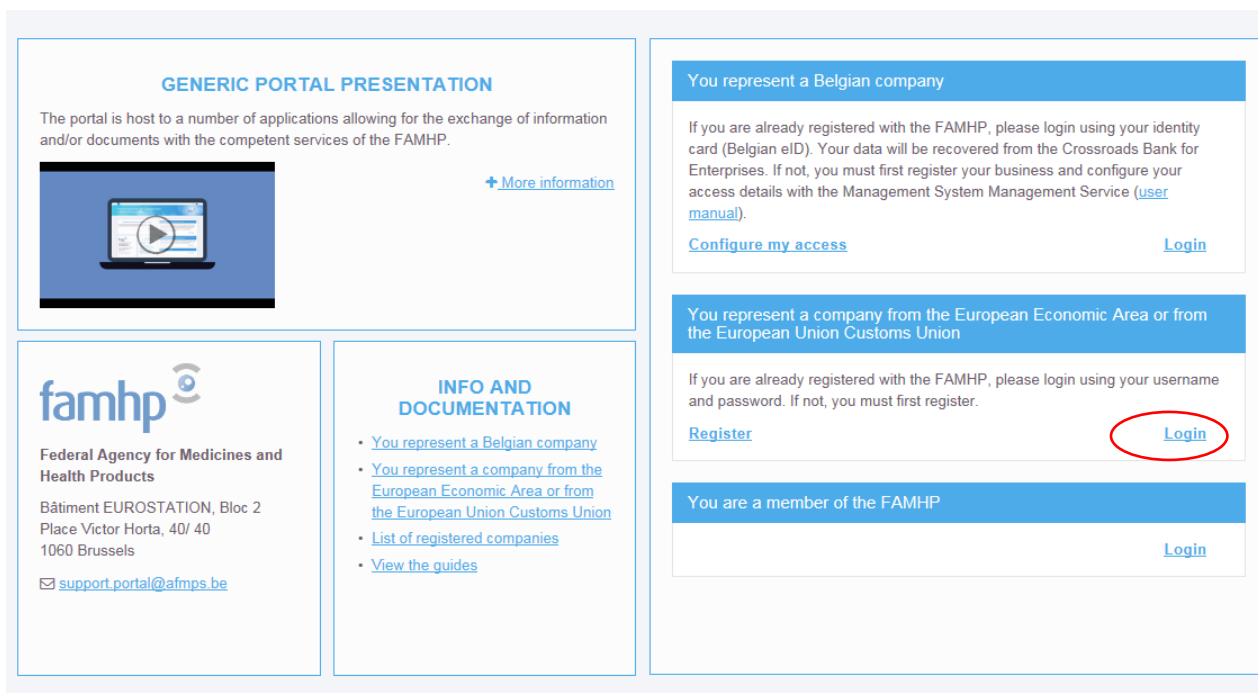
Nederlands ∨

Aanmelden voor **Portaal MEDSEIP**

Kies een beheerder om verder te gaan:
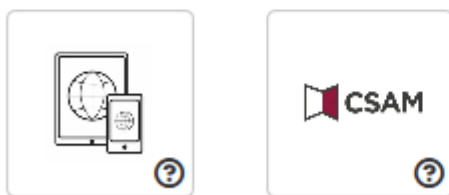
Figure 19

4. Enter your login (your NISS number) and your temporary password (figure 19);

SAA_AUTHENTICATION

Username or email   Insérer votre numéro NISS

Password

Forgot Password?   Log in

Figure 20

.be
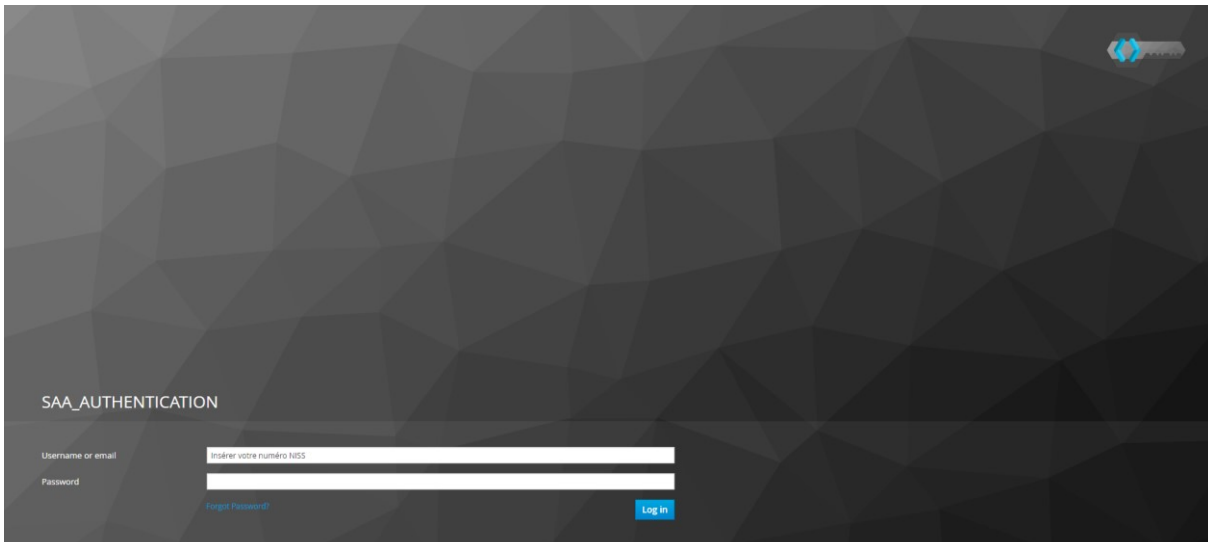
5. Open the Google Authenticator app and scan the QR code using your phone (figure 20);
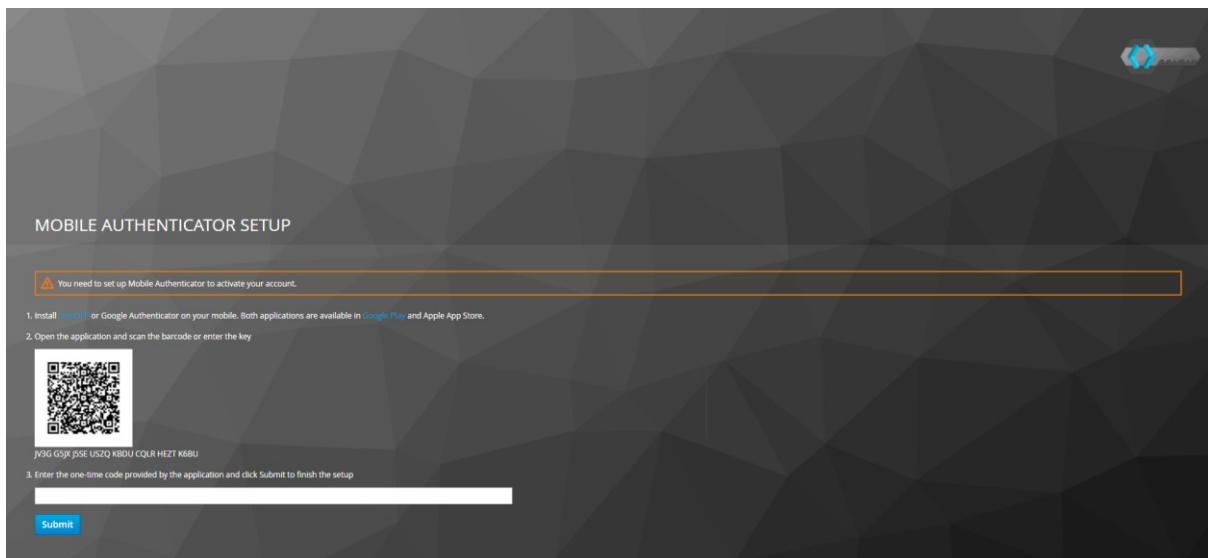
Figure 21
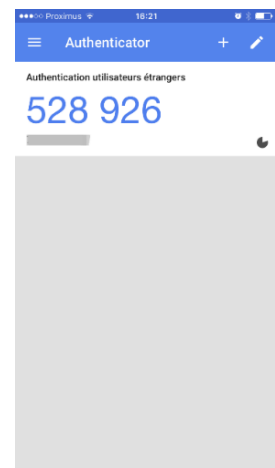
6. Enter the one-time passcode (generated by your smartphone) into PC screen _____ . This code is renewed every 30 seconds.
7. If you're logging in for the first time the application will ask you to enter a new password (figure 21).

Figure 22

1.   Go to the FAMHP portal. Click "Login".

 Then "Continuer par AFMPS"**Fout! Verwijzingsbron niet gevonden.**

3.   Log in as an enterprise from the European Economic Area or the European Union Customs Union by clicking "Login"

4.   and "   "

5 DESCRIPTION OF THE APPLICATION

This portal has been developed as part of the FAMHP Medical Device department's control policy reform project. Other applications will be gradually added as they are developed.

The goals are:
- Streamlining the market monitoring activities by the competent departments of the FAMHP;
- Optimising the planning and execution of inspections through the use of risk assessments;
- Reinforcing administrative simplification (adhering to the "only once" principle, digitalisation of administrative processes);
- Strengthening transparency and synergies with all stakeholders.

The portal hosts a number of applications allowing for the exchange of information, data and documents with the competent services of the FAMHP.

5.1 USE OF THE PORTAL

Before logging in via the button available on the FAMHP portal's home page, make sure you have your NISS number (login), your password and your temporary password generator (TOTP app) on your phone or your eID at hand.

We recommend you to consult the "Info and documentation" tile on the home page. It contains a source of information that will guide you and/or answer any initial questions you might have.

In each of the available applications, you will find small question mark icons . These are tooltips, they contain explanatory and/or additional information. We recommend you to consult them when you start using the portal.

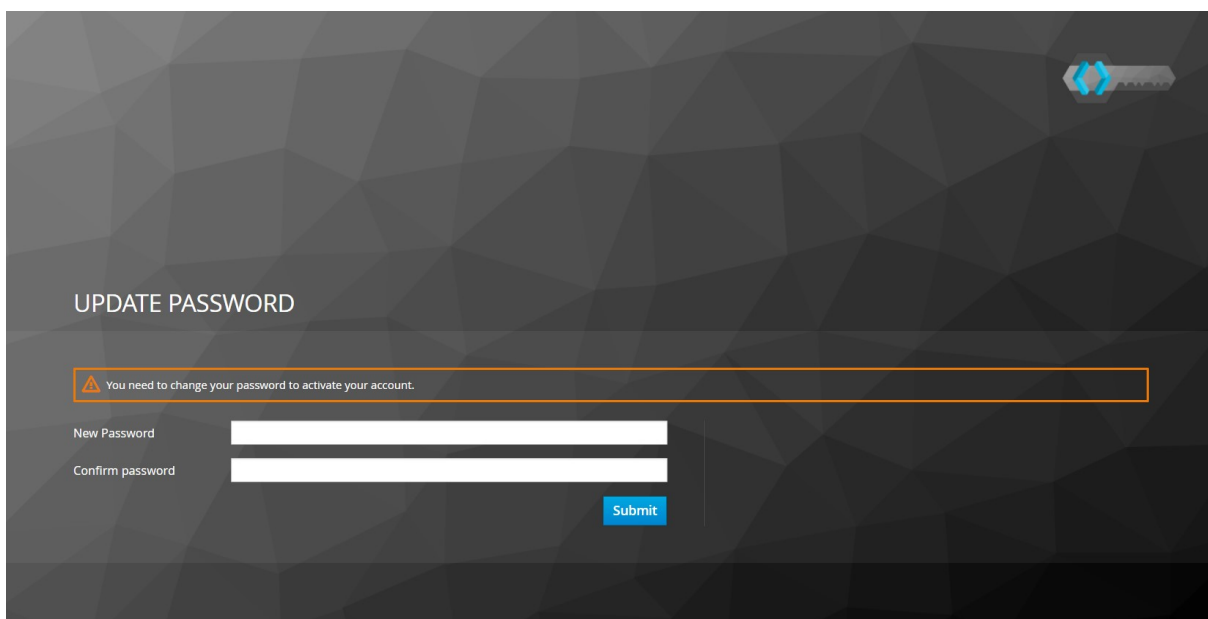If you have any questions or experience any technical difficulties while using these applications, please contact portal.support@afmps.be.

5.2 MY ENTERPRISE

The tile "My enterprise" contains the enterprise data extracted from the CBE, as well as additional information concerning the legal representatives, business sites and contact persons.

You can save, view and modify information about your enterprise in this tile. For a user of an enterprise the first time connecting to the FAMHP application, the "Register" button in the right lower bottom of the screen confirms the registration of the data of the company. Then other tiles will become accessible.
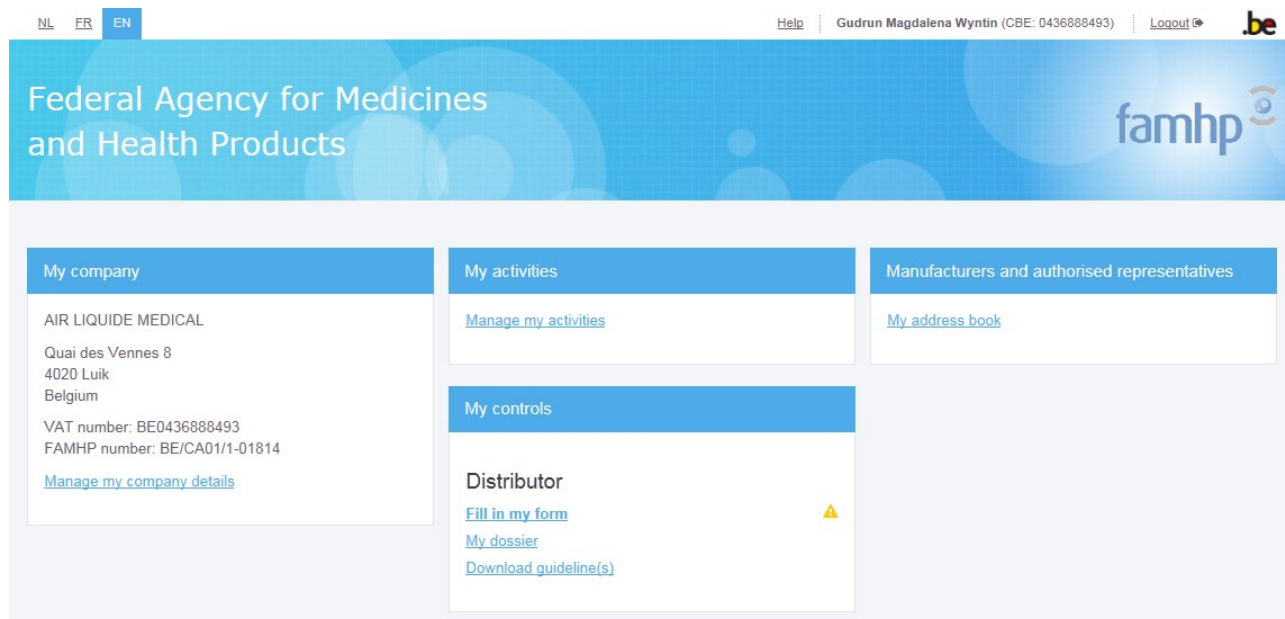
Figure 33

5.3 MY ACTIVITIES

The tile "My activities" contains the enterprise's areas of activity (e.g. distribution, importer, manufacturer, etc.) with risk classifications, activity premises and contact persons.

You can report, view, modify and deactivate your enterprise's activities from this tile.

FAQ activities

Once an activity is defined, the company get its FAMHP number and the company is listed in the public list.

5.4 MY CONTROLS

The tile "My Controls" is dedicated to the exchange of data and documents with the FAMHP's inspection services and is intended to offer flexibility. (inspection.meddev@fagg-afmps.be)

You can make any necessary changes and amendments after the first use.

In particular, this tile invites you to fill in the form foreseen by law and enhances the communication of inspection reports, the exchange of corrective action plans and other useful documents between the company and the FAMHP's inspection departments.

By taking into account the information and data exchanged, "My Controls" simplifies the performance of risk assessments by the FAMHP's inspection departments.

Thanks to this portal, the FAMHP has a dynamic and scalable database allowing to streamline planning and execution of market monitoring missions.

5.5 MANUFACTURERS AND AUTHORISED REPRESENTATIVES

The tile "Manufacturers and authorised representatives" allows:

- distributors reported to the FAMHP to add/modify/delete the identity and location (country) of their suppliers, in particular their manufacturers and authorised representatives;
- manufacturers reported to the FAMHP to register the medical devices they sell in Belgium;

- authorised representatives reported to the FAMHP to report (add/modify/delete) all of the companies they represent.

5.6   MY CONTRIBUTIONS

Companies have to pay a yearly contribution based on the annual revenue in Belgium.
Distributors delivering directly to private persons declare this in order to be freed from this contribution.

Contributions.meddev@fagg-afmps.be

6 HELP

If you have any questions or need help with access, the appointment of a CAM on www.csam.be, the activation of the quality or user management within your enterprise, you can contact the Social Security contact centre:
- by telephone on + 32 (0)2 511 51 51,
- by email at centredecontact@eranova.fgov.be.

For questions relating to the use of the FAMHP portal, please send an email to support.portal@afmps.be.

7 FAQ

1. I've followed the registration procedure, but my company does not appear in the list of companies recognised by the FAMHP (see Public Search)
   ➢ This means you didn't enter your activities (manufacturer, distributor, etc.) in the "My activities" tile. Please log in to the portal and update your activities.

2. What is a NISS number?
   ➢ To access Belgian federal applications, a Non-Belgian citizen will need a NISS number, which is a Belgian Social Security Identification Number. This number starts with your year of birth, month of birth + 40, day of birth and ends with 5 figures. You can apply for this number through the Limosa service.

3. I don't have access to the "My medical devices" app
   ➢ Make sure you have access to the "MEDSEIP" ("Access to our webportal") as described in 3.2.2 (Figure 16).

4. The authorised representative has not received the temporary login and password needed to log in to the platform (see 0)
   ➢ Registration emails are sent electronically to the legal managers of your enterprise. If they have not received this information, please ask them to check their junk mail folder.

5. I haven't received my TOTP Password. What should I do?
   ➢ Please check the junk mail folder in your mailbox.
   ➢ If it's not there, please request a new password by following the steps in point 4.1 and clicking "Forgot Password" Figure 20).
   ➢
6. I have a new phone. How do I get my otp code on it?
   ➢ Use the link "Forgot Password" on the login page with your email address
   ➢ You should receive an email containing a link. This link can only be clicked once within 5 minutes. Via this link you can scan QR-code with your new phone.
   ➢ You can click "Forgot Password" without any restriction.

7. I would like to appoint the management of my data on the FAMHP portal to someone who does not have a NISS (Belgian Social Security Identification) number.
   ➢ Create this person as a new contact in the webportaal (chapter 3.2.3). An automatic mail with the login and temporary password should be sent.
   ➢ Once this person got the national number (SSIN, NISS in French), this should be added them to the list of users or co-managers on CSAM by following the steps in point 3.3.2.

8. I cannot activate applications on CSAM. What should I do?
   ➢ Make sure the designation of "Institution in the healthcare domain" ("**Institution liée au domaine de la santé**") is active (see 3.2.1) and then follow the steps in 3.2.2.

9. Belgians: Where can I buy a card reader?
    ➢ Please see this <u>link.</u>

10. Is it possible to log in to the FAMHP Web portal with a resident identity card?
    ➢ No, it is not possible. Only a Belgian identity card can be used.

11. I have sent my PAM application form to Eranova (see 3.1). How long will it take to process?
    ➢ This procedure takes around 15 days.

12. Where can I find the national registration or NISS number?
    ➢ This number has been sent by an automatic mail.
    ➢ email the name, date and place of birth and email address of that person to the helpdesk

13. My second TOTP code is still not working (see steps described in 4.1). What should I do?
    ➢ Uninstall the TOTP login and authenticator app.
    ➢ Either reinstall another authenticator app (Google Authenticator/Microsoft Authenticator/Authy, etc.); Then synchronise the time zones. Google Authenticator example: access the main menu for the Google Authenticator app -> Settings-> Time correction for codes -> Sync now
    ➢ Or install the authenticator on another device. Use https://authy.com to install and test it.
    ➢ Use the Google Chrome or Internet Explorer browser.

14. I am unable to log in. The authentication system says my profile is invalid
    ➢ There are three possible reasons for this error:
    i.   Could you try logging in again? Sometimes, the social security access authorisation is not sent directly to our apps. You have to wait until the following day to be able to log in.
    ii. Your company is not designated as an "Institution in the domain of healthcare". (see 3.2.1).
    iii. You are not a named manager or are not flagged as a user of our apps (see 3.2.2)
    iv. If none of the above solutions worked for you, please send us an email with a screen print of the social security page with your access details.

15. I am already registered with the FAMHP. Do I need to re-register?
    ➢ Yes, you will need to register again. The whole actor registration and information procedure has been modified since December 21st 2017. This new procedure is completely free of charge