Generic online registration

Find out what to do, who to contact, advice and tips on how to best prepare for the process, as well as all the documentation and useful resources.

Getting to know you

I assess my compliance with the requirements of the standards.

START

I have read the interoperability and safety guidelines for digital medical devices.

ANS

Certification of conformity

This stage verifies the conformity of your solution's supporting documents.

DEPOSIT

I submit my compliance file on the Convergence platform

ANS

CERTIFICATION

I submit proof of compliance

ANS

Submitting my application

At this stage, my application is evaluated. In the event of a favorable decision by the ministers, I receive the standard reimbursement.

APPLICATION

I submit my application on the "Démarches Simplifiées" platform

APPLICATION

My candidacy is evaluated by the ministers

I have read the interoperability and safety guidelines for digital medical devices.

Prerequisites

The solution must be CE marked.

01. I identify the base documentation that concerns me

START ANS

I have read the interoperability and security guidelines and the technical specifications that apply to the remote monitoring DMN.

I consult the repository

I download the generic line requirements

02. I'm upgrading my solution

I'm bringing my solution into line with the standards

Point of attention: Updating your digital device may have an impact on your CE marking.

Need help?

If you have any questions about your solution's compliance with the safety and interoperability standards, please contact your notified body.

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Previous

Next

I submit my compliance file on the Convergence platform

03. Login to my account

ADMINISTRATIVE ANS

I do not yet have an account on the Convergence platform

Delay 3 days to open an account

- I create my account on the iSC Identity Provider subsequently allowing me to access the Convergence platform.
- Supporting documents to be provided: Kbis of the company and verification of the identity of the corporate officer on the basis of a valid ID.

Point of attention: To sign up to a scheme, the representative of your structure must be registered on the Identity Provider as its representative.

I already have an account on the Convergence platform

Login

04. I submit my file to Convergence

ADMINISTRATIVE ANS

I submit my administrative file on the Convergence platform

You will be asked for a list of documents to be submitted.
In particular, don't forget to bring the following documents with you:

- Functional documentation
- Personal data protection certificate
- CE marking declaration

Consult the filing guide on Convergence for all the documents you need to provide.

For information: I'm informed by e-mail about the progress of each stage of my application.

05. My file is studied

ADMINISTRATIVE ANS

My request will be considered

The ANS examines the admissibility of my application.

Help wanted

In case of difficulty, you can contact the team in charge via the Convergence platform's internal messaging system.

06. My request is validated

ADMINISTRATIVE ANS

I receive validation of the admissibility of my application

I will be informed by e-mail about the validation of my file.

Previous Next

I submit proof of compliance

07. I deposit the evidence

CERTIFICATION ANS

I submit proof of compliance

Once my application has been validated, I respond to requests for additions to my file, file proofs of compliance and enter the specific requirements of the generic lines.

If any of the evidence is invalid, I am contacted by e-mail via the Convergence platform and given the opportunity to correct my digital medical device, so that it is compliant.

If I'm part of ETAPES

Following the publication of the decrees for the 4 LGs (Diabetes, Heart Failure, Renal Failure, and Respiratory Failure), I must make a complete deposit of proofs on Convergence.

Once I file my evidence, I receive a **provisional certificate by ANS**. This certificate is issued subject to proof compliance before 31/12/2023.

Point of attention: Once I have obtained the provisional certificate, I can already complete my **request for billing code** via a form on the Simplified procedures portal (I consult step 9 of the guided path). I then get a billing code by indication, within **15 days**, allowing me to bill under ordinary law.

Need help?

In case of difficulty, you can contact the team in charge via the Convergence platform's internal messaging system.

08. I receive certifications

FINALISATION ANS

I obtain certificates of conformity

Once my application has been validated, I will receive my compliance certification documents by email, as well as information for the rest of the digital medical device compliance certification procedure.

I receive the following two certifications:

- the **interoperability and safety repository** for DMNs
- compliance with the **minimum requirements generic lines** for each of the pathologies

.

Previous

Next

I submit my application on the "Démarches Simplifiées" platform

Prerequisites

The solution must have:

- the CE marking
- the certificate of compliance with interoperability and safety standards issued by the ANS
- the validation of compliance with generic line specifications issued by the ANS

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09. I'm connecting to the Démarches Simplifiées platform

ADMINISTRATIVE

I do not yet have an account on the Démarches Simplifiées platform.

Two connection solutions are possible:

1. Connection via FranceConnect

2. Create an account in ligne and receive an e-mail to validate registration

For more information, consult the guide de la démarche.

I already have an account on the Démarches Simplifiées platform

Login

10. I submit my application on the

APPLICATION MSS

Démarches Simplifiées platform

I submit my application via the Démarches Simplifiées platform

When I start completing the process, I receive an e-mail telling me that I've started a **draft**. Then, when I click on "*File the application*", I receive an e-mail confirming that the application has been filed.

Point of attention: the **estimated filling time** is **30 minutes**.

Help wanted

If you have any questions, please send an e-mail to dss-referencement@sante.gouv.fr

Previous

Next

My candidacy is evaluated by the ministers

11. My application is evaluated

APPLICATION MSS

My candidacy is evaluated by the ministers

Delay 60 days

My candidacy will be evaluated by the ministers in charge of health and social security.

The processing time is **60 days** from receipt of my application.

If the parts supplied do not contain all the necessary information

Delay 15 days

- I am notified via e-mail by the ministers about the additional information I must provide within **15 days**. During this time, **the period referred to in the previous paragraph (60 days) is suspended** from the date of this notification and until the date of receipt of the elements or information requested.
- If I do not send the requested elements within the time limit, my registration request is deemed abandoned and I will be informed electronically and via the platform.

12. I get my money back

FINALISATION CNAM MSS

I get the standard reimbursement

If my application is complete, I will receive the code assigned to me by e-mail.

The list of codes is updated on the website of the ministers in charge of health and social security. Assurance maladie updates its reimbursement bases accordingly.

These codes will enable me to be reimbursed on the line(s) allocated and the ministers to have an identification of the operators on each generic line.
My common law reimbursement is valid according to the duration of the corresponding generic line.

Please note: In the event of an unfavorable decision, the decision to refuse the allocation of an individual identification code is sent electronically to the operator, with a statement of the reasons for the decision and the applicable appeal procedures and deadlines.

Previous

You have completed your course

You are aware of all the steps involved