

## Brand name 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-UP

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.

DÉPÔT

I submit my compliance file on the Convergence platform

ANS

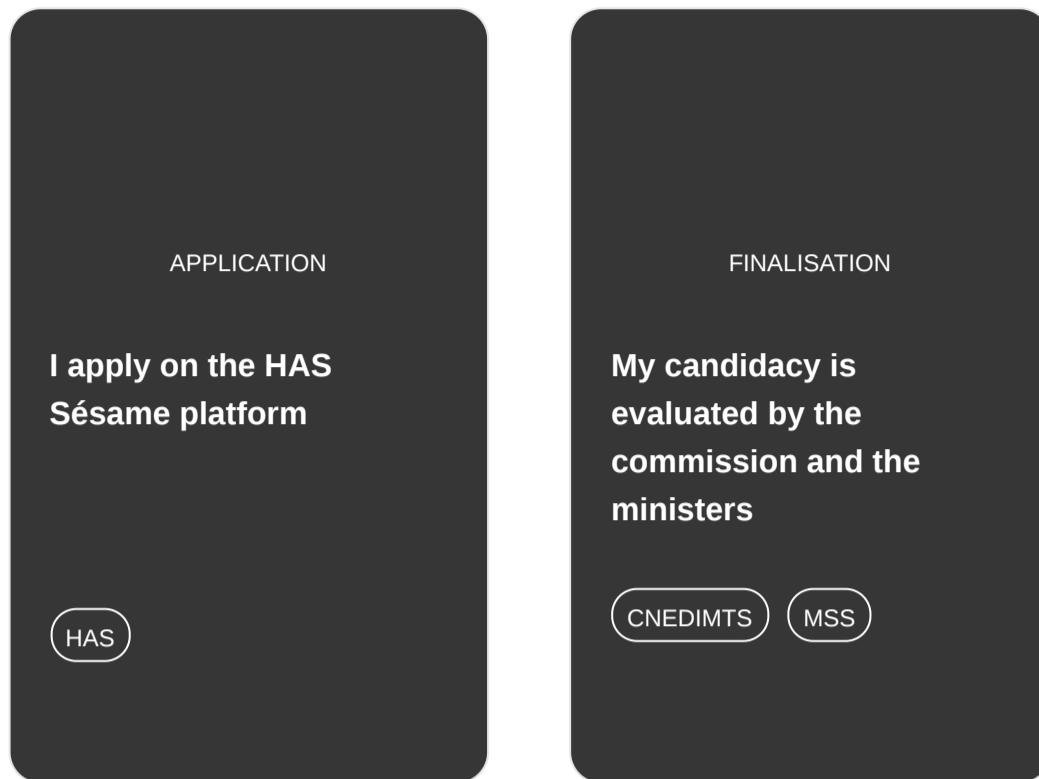
CERTIFICATION

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.



# 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-UP **ANS**

### I have read the safety and interoperability guidelines

[I consult the repository](#)

## 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 difficulty in ensuring that your solution complies with the safety and interoperability reference framework, you can address your questions to your notified body.

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## 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 to find out all the documents you need to provide.

**For information:** I am informed by e-mail on 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.

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## 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 and file proof of my compliance.

If any of the evidence is invalid, I have the option of correcting my digital medical device, so that it complies.

#### Need help?

Contact the team in charge via the Convergence platform's internal messaging system.

### 08. I receive certification

FINALISATION **ANS**

#### I get the certificate 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.

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## I apply on the HAS Sésame platform

### Prerequisites

The solution must have:

- the CE mark
- the certificate of compliance with current interoperability and security standards previously issued by the Agence du numérique en santé (ANS).

### 09. I connect to the Sésame platform

ADMINISTRATIVE HAS

#### I do not yet have an account on the Sésame platform

**Point of attention:** To submit a file on Sésame, I must have an access account to the platform. I can request, from the HAS, the creation of my account through the [corresponding form](#).

I find all the access modalities in the dedicated [FAQ](#).

#### I already have an account on the Sésame platform

Login

### 10. I would like to be accompanied

APPLICATION HAS

#### I would like support before submitting my application

The HAS offers, for industrialists who wish, appointments before the submission of the file:



- some [early meetings](#) to discuss a study protocol;
- from [rendez-vous pré-dépôt](#) to discuss any questions you may have when building your dossier.

These meetings are free and confidential.

APPLICATION HAS

## 11. I submit my application on the Sésame platform

### I apply via the HAS Sésame platform

I find the [FAQ](#) dedicated from the Sésame platform.

#### Points of attention:

- The file filed on Sésame is accessible to the ministers in charge of health and social security and is worth filing with the ministers.
- I must e-mail a copy of my application to the relevant national professional councils (CNP).

Each time my status changes, I receive notification by e-mail (if I've chosen this option) or directly on the platform.

### Help wanted

At any time, I can check the status of my file on Sésame.

If you have any difficulties, you can e-mail your questions to [guichetnumerique@has-sante.fr](mailto:guichetnumerique@has-sante.fr)

APPLICATION MSS

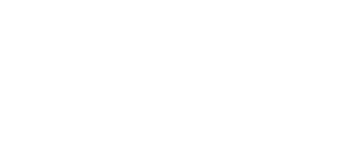
## 12. I receive confirmation of my application

### I receive an acknowledgement of receipt

If my file is complete, I receive an acknowledgement of receipt (AR) from the Ministry. If any information is missing, I am informed by e-mail.

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## My candidacy is evaluated by the commission and the ministers

### 13. The commission evaluates my application

APPLICATION **CNEDIMTS**

#### My application will be examined by the

- If I have received an AR of the file from the ministry, my application will be studied first by the CNEDIMTS commission.

#### If the parts supplied do not contain all the necessary information

**Delay** 10 days (or more)

- I am notified by the HAS or by the ministers in charge of health and social security of the additional information I must provide within a minimum of 10 days.
- If I fail to submit the requested information within the allotted time, my application for registration is deemed abandoned.

### 14. I receive a notice

APPLICATION **CNEDIMTS**

#### I receive a favorable opinion from the commission

**Delay** 90 - 70 days

- The commission's opinion is communicated to me within 90 days, 70 days if the telemonitoring activity benefits from anticipated reimbursement, and it is published on the HAS website.
- I receive a favorable or unfavorable opinion via the Sésame platform.

## I can make my observations

**Delay** 10 days

Once the draft opinion is returned to me by the commission. I have 10 days following receipt to **request to be heard by the commission.**

**Point of attention:** in this case, the hearing date is set no later than 45 days following receipt of your request. Upon reasoned request to the commission by the ministers in charge of health and social security, this timeframe may be reduced to one month.

**Please note: in this case, the hearing date is set no later than 45 days following receipt of your request.**

At the end of this phase, the opinion is communicated to me via the Sésame platform, as well as to the CNPs and the ministers, and it is published on the HAS website.

## 15. My application is evaluated

APPLICATION **MSS**

### My candidacy is evaluated by the ministers

- Once I receive the commission's opinion, my application will be considered by the ministers in charge of health and social security.

### If the parts supplied do not contain all the necessary information

**Delay** 10 days (or more)

- I am notified via e-mail by the ministers of the additional information I must provide within a minimum of 10 days.
- If I fail to submit the requested information within the allotted time, my application for registration is deemed abandoned.

## 16. I get my money back

FINALISATION **MSS**

## I get the standard reimbursement

**Delay** 120 days

- The ministers' decision is set by decree within 120 days of acknowledgement of receipt.
- In the event of a positive decision, the order will be published in the Journal Officiel. In the event of a refusal, I receive a letter from the ministers.
- I can reapply on the Sésame platform without applying on the ANS site if my product has not undergone any technical evolutions and if the ANS referentials have not evolved.
- My common law reimbursement is valid for a maximum of 5 years, which is specified in the order in the Journal Officiel. If my certificate of conformity is still compliant, I can apply to renew my registration directly on the Sésame platform.

**Please note:** the application must be submitted no later than 120 days before the expiration of the registration period.

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**You have completed your course**

**You are aware of all the steps involved**