Registration as a brand name

Find below the actions to be taken, who to contact, advice and tips to best prepare your approach, as well as all the useful documentation and resources

Learning more

Assess your compliance with the standards

START-UP

Learn about the interoperability and security standard for digital medical devices

ANS

Certification of compliance

This step involves verifying the compliance of your's solutions documents

DÉPÔT

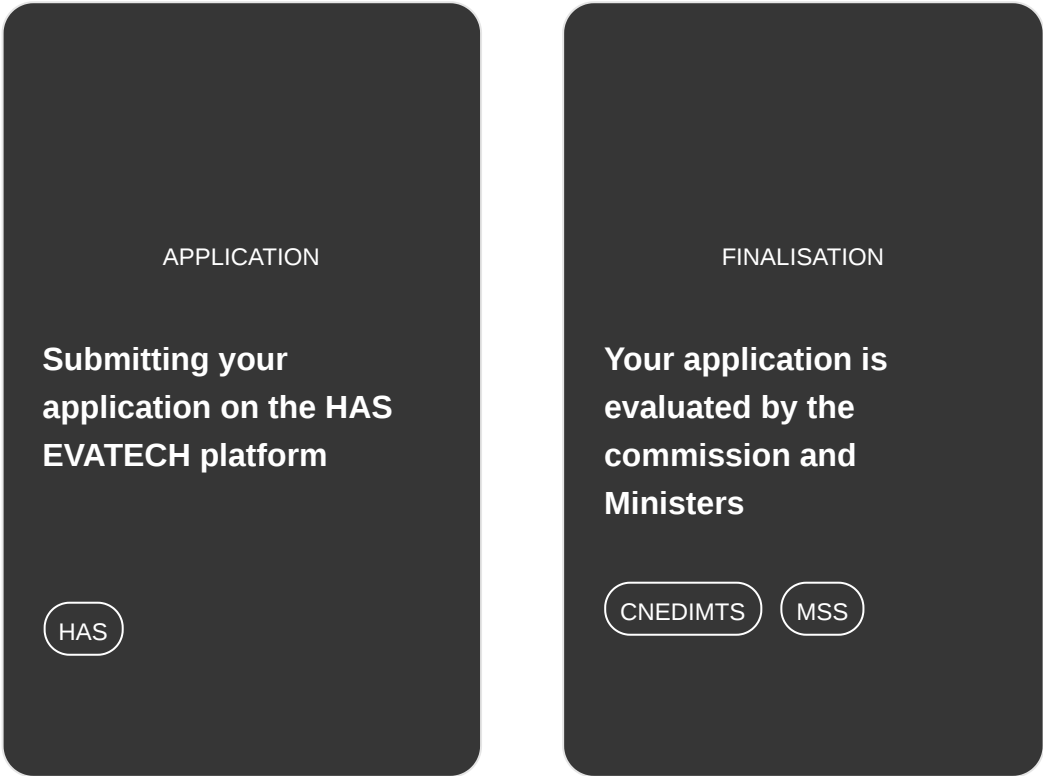**Submitting your compliance application on the Convergence platform**

ANS

CERTIFICATION

Submit evidence of your compliance

ANS

Submitting your application

This step involves the evaluation of your application. If the ministers approve it, you become eligible under the standard system

APPLICATION

Submitting your application on the HAS EVATECH platform

HAS

FINALISATION

Your application is evaluated by the commission and Ministers

CNEDIMTS   MSS

Learn about the interoperability and security standard for digital medical devices

Prerequisites

The solution must have earned CE marking.

01. Identify the core documentation that is relevant to you

START-UP ANS

Learn about the security and interoperability standard

Download the standard

02. Upgrade your solution

Bring your solution into compliance with the standard

Matter of note: Updating your digital device may have an impact on your CE marking.

Need help?

If you're having any difficulties with your solution's compliance with the security and interoperability standard, you can direct your questions to your notified body.

Submitting your compliance application on the Convergence platform

03. Logging in to your account

ADMINISTRATIVE ANS

If you don't have an account on the Convergence platform yet

Delay 3 days to open an account

- Fill out the registration form directly on Convergence
- You'll receive a confirmation email, containing your login and a link to set your password.
- Required documentation: Company's kbis form / copy of a valid ID of the corporate officer.

If you already have an account on the Convergence platform

Logging in

04. Submitting your application in Convergence

ADMINISTRATIVE ANS

Submitting your administrative application on the Convergence platform

A list of documents will be provided for you to submit.
Please remember to have the following documents on hand:

- Functional documentation
- Statement of personal data protection
- CE marking declaration

Read the filing guide on Convergence to find out all the documents you will need to provide.

For information: You will be informed by e-mail whenever your application reaches a new stage.

05. Your file is reviewed

Your request is reviewed

The ANS reviews the eligibility of your file.

Need help

If you have any problems, you can send your questions by e-mail to telesante@esante.gouv.fr

06. Your request has been approved

You get approval for your application's eligibility

You will be informed by e-mail that your file has been approved.

07. Submit evidence

CERTIFICATION ANS

Submit evidence of your compliance

Once your application has been approved, answer any requests for further information, and file evidence of your compliance.

If any of the evidence is invalid, you have the option to correct your digital medical device to make it compliant.

Need help?

Contact: telesante@esante.gouv.fr

08. Get certification

FINALISATION ANS

You'll receive the certificate of compliance

You'll receive the certificate of compliance with the interoperability and security framework by e-mail. You can download your certificate at any time directly from your Convergence account.

Submitting your application on the HAS EVATECH platform

09. Logging in to your EVATECH platform

ADMINISTRATIVE HAS

If you don't have an account on the EVATECH platform yet

Matter of note: In order to submit a file to EVATECH, your organisation and user profile must first be registered at "MON PORTAIL HAS".

Learn how to access it in the dedicated FAQ.

If you already have an account on the EVATECH platform

Logging in

10. Receiving guidance

APPLICATION HAS

If you would like to receive guidance before submitting your application

The HAS offers appointments to manufacturers who wish to have one before they file the application:

- early-stage meetings to discuss a study protocol

- pre-filing meetings to discuss the questions you have when putting together your application.

These meetings are free of charge and confidential.

11. Submitting your application on the EVATECH platform

APPLICATION HAS

Submitting your application via the HAS EVATECH platform

Read the dedicated [FAQ](#) from the EVATECH platform.

Matter of note:

- The application filed on EVATECH is accessible to the Ministers of Health and Social Security and is considered filed with the Ministers.
- You must email a copy of your application to the appropriate National Professional Council (CNP).

Each time your status changes, you'll get a notification by email (if you've chosen this option) or directly on the platform.

Need help

Your can check the status of my file on EVATECH at any time.

If you have any problems, you can send your questions by e-mail to guichetnumerique@has-sante.fr

12. Get confirmation of your application

APPLICATION MSS

Get an acknowledgement of receipt

If your file is complete, you'll receive an acknowledgement of receipt (AR) from the Ministry. If any information is missing, you'll be informed by e-mail.

13. The commission evaluates your application

APPLICATION   CNEDIMTS

Your application is reviewed by the commission

- If you've received an AR of the file from the Ministry, your application will be reviewed first by the CNEDIMTS commission.

If the documents provided do not contain all the necessary information

Delay   10 days (or more)

- You'll be notified by the HAS or by the Ministers of Health and Social Security about what additional information must be provided within a period of no less than 10 days.

- If you don't submit the requested information by the deadline, your application for eligibility will be considered void.

14. You get an opinion

APPLICATION   CNEDIMTS

You get a favourable opinion from the commission

Delay   90 - 70 days

- The commission's opinion will be communicated to you within 90 days, or 70 days if the remote monitoring activity is covered by the advance payment system, and it is published on the HAS website.

- You get a favourable or unfavourable opinion via the EVATECH platform.

You can provide comments

Delay 10 days

Once the draft opinion has been returned to you by the commission. You have 10 days following receipt to:

- Send any written comments to the commission via the EVATECH platform, with an email copy to the Ministers at DSS-SD1C@sante.gouv.fr.
- Or request a hearing before the commission.

Please note: If choosing this option, the hearing date is set within 45 days after receiving your application. Upon a reasoned request from the Ministers of Health and Social Security to the commission, this period may be reduced to one month

At the end of this phase, the opinion is communicated to you via the EVATECH platform, as well as to the CNPs and Ministers, and it is published on the HAS website.

15. Your application is evaluated

APPLICATION MSS

Your application is evaluated by the Ministers

- Once you receive the commission's opinion, your application will be reviewed by the Ministers of Health and Social Security.

If the documents provided do not contain all the necessary information

Delay 10 days (or more)

- You'll be notified by e-mail by the Ministers about what additional information must be provided within a period of no less than 10 days.
- If you don't submit the requested information by the deadline, your application for eligibility will be considered void.

16. You've achieved

FINALISATION MSS

Become reimbursable under standard system

Delay   120 days

- The Ministers' decision is set by order within 120 days of the acknowledgement of receipt.

- If the decision is positive, the order will be published in the Official Journal. If the application is rejected, you'll receive a letter from the Ministers.

- You can reapply on the EVATECH platform without applying on the ANS website if your product has not undergone any technical changes and if the ANS standards have not changed.

- Your eligibility for reimbursement under the standard system is valid for up to 5 years; how long is specified in the order in the Official Journal. If my certificate of compliance is still valid, you can apply to renew your registration directly on the EVATECH platform. Please note: The application must be submitted no later than 120 days before the expiration of the registration period.