SmartSuite

Framework / Privacy / Other

Hébergement de Données de Santé (HDS) – Référentiel de certification v2.0 (arrêté du 26 avril 2024)

France's HDS certification is mandatory for hosting personal health data for third parties under article L.1111-8 CSP; référentiel v2.0 applies to every certificate since 16 May 2026.



What it is

HDS (Hébergement de Données de Santé) is the French certification that any person or company must hold before hosting personal health data on behalf of third parties, a legal obligation set by article L.1111-8 of the Code de la santé publique. It covers health data collected during prevention, diagnosis, care or social and medico-social follow-up, whether the host is a cloud provider, a software vendor, a data center operator or a hospital hosting for others.

At a glance

PUBLISHER
Ministry of Health (référentiel approved by arrêté); operated by the Agence du Numérique en Santé (ANS); certificates issued by COFRAC-accredited bodies

TYPE
Certification / Assurance Program

VERSION
HDS certification référentiel v2.0 (arrêté of 26 April 2024)

EFFECTIVE
May 16, 2024 (JO publication); the only basis for certificates since May 16, 2026

DOMAIN
Privacy

FAMILY
Other

REGION
France

INDUSTRY
Healthcare & Life Sciences

ADOPTION MODEL
Certification

IMPLEMENTATION COMPLEXITY
High

Source: esante.gouv.fr/produits-services/hds

Why it matters

- **A statutory duty, not a preference** Article L.1111-8 of the Code de la santé publique requires certification for anyone hosting personal health data on behalf of the data producers or the patient.
- **Six defined activities** Article R.1111-9 lists the activities a certificate can cover, from physical sites to backup, so scope is explicit on every certificate.
- **EEA storage** Requirement 28 of v2.0 obliges the host and its subcontractors to store health data inside the European Economic Area.
- **Contract transparency** Requirements 29 and 30 make the host document transfer safeguards, the non-European laws it is exposed to, mitigation measures and residual risks in the contract.

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How SmartSuite supports France HDS

Activity Scope Register

Record which of the six article R.1111-9 activities each certificate covers, per site, with the certification body, certificate dates and the EEA location of every site.

Requirement Library with Owners

Hold the v2.0 requirements as controls with an owner, the ISO/IEC 27001:2022 clause they share, evidence links and the next review date.

Subcontractor Guarantee Table

Track every subcontractor, its storage location, the non-European laws it is exposed to and the guarantees given, the table the ANS expects hosts to maintain.

Contract Clause Tracker

Follow the customer contract updates for requirements 17 to 27, including the transfer disclosures, with status, signatory and completion date.

Transfer Map and URL Record

Keep the published transfer map and the requirement 31 URL as a controlled record, with the review history sent to the certification body.

Audit and Finding Workflow

Run certification and surveillance audits, log nonconformities, assign corrective actions and report closure to the certifier.

Common framework mappings

SOC 2 | GDPR | HITRUST CSF v11.5 | ISO 27001:2022 | ISO 27002:2022 | ISO 27017 | ISO 27701

Official resources

Certification HDS - Hébergeur de Données de Santé

Provides detailed specifications for obtaining HDS certification in France.

esante.gouv.fr/produits-services/standard-hds

HDS Guidelines for Cloud Service Providers

Outlines requirements and procedures for cloud services seeking HDS certification.

esante.gouv.fr/produits-services/hds-cloud-guidelines

HDS Compliance Implementation Guide

Describes practical steps for achieving compliance with HDS certification standards.

esante.gouv.fr/produits-services/hds-implementation-guide

Frequently asked questions

Who must hold HDS certification?

Any natural or legal person that hosts personal health data on behalf of the persons who produce or collect it, or on behalf of the patient, under article L.1111-8 of the Code de la santé publique. The data concerned is health data collected during prevention, diagnosis, care or social and medico-social follow-up. Since the SREN law of 21 May 2024 this also covers electronic archiving services that keep such data for third parties.

What are the six HDS hosting activities?

Article R.1111-9 lists them: providing and maintaining physical sites, hardware infrastructure, virtual infrastructure and the application hosting platform; administering and operating the information system containing health data; and backing up health data. A certificate names the activities it covers, and only sites in the European Economic Area can be certified for activities 1, 2 and 6.

What changed with référentiel v2.0?

Version 2.0, approved by the arrêté of 26 April 2024 and published on 16 May 2024, aligned the ISMS basis with ISO/IEC 27001:2022 and added sovereignty requirements: storage in the EEA (requirement 28), GDPR adequacy or article 46 safeguards for remote access from outside the EEA (29), contractual disclosure of non-European law exposure, mitigation and residual risks (30), and a published transfer map (31).

Is HDS v1.1 certification still valid?

No. Certification bodies had until 16 November 2024 to move to v2.0 and hosts certified under v1.1 had until 16 May 2026. The ANS states that after 16 May 2026 every valid HDS certificate attests conformity to v2.0 only.

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Who audits and certifies HDS hosts?

Certification bodies accredited by COFRAC assess the host against the référentiel and issue the certificate; the ANS publishes the list of certified hosts and the transfer URLs required by requirement 31. The ministry approves the référentiel by arrêté, and the ANS runs the scheme.

License included / downloadable: Yes The HDS référentiel and the Code de la santé publique provisions are public texts published in the Journal officiel and on esante.gouv.fr; certification itself is a paid service from an accredited body.

Full framework page and mappings: smartsuite.com/frameworks/france-hds-healthcare-data-hosting-certification

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