SmartSuite

Framework / Privacy / Other

Hébergement de Données de Santé (HDS) – Référentiel v3.0

France HDS is a certification requiring hosting providers to secure, manage, and protect personal health data processed in France.

MINISTÈRE
DE LA SANTÉ, DES FAMILLES,
DE L'AUTONOMIE
ET DES PERSONNES HANDICAPÉES

Liberté
Égalité
Fraternité

What it is

France HDS — Healthcare Data Hosting Certification is a regulatory framework that helps organizations ensure the security, confidentiality, and availability of healthcare data processed or hosted within France. It establishes mandatory requirements for hosting providers that manage personal health information, aiming to protect sensitive medical records against cybersecurity threats and data breaches.

Issued and overseen by the French Ministry of Health and the Agence du Numérique en Santé (ANS), the HDS certification is required for any organization storing, processing, or transmitting healthcare data in France. The framework covers areas including physical and logical security controls, incident response, privacy governance, risk management, and operational resilience in line with local and EU data protection laws.

At a glance

PUBLISHER Ministère des Solidarités et de la Santé	TYPE Certification / Assurance Program	VERSION HDS Certification Framework (current requirements)
EFFECTIVE January 1, 2020	DOMAIN Privacy	FAMILY Other
REGION France	INDUSTRY Healthcare & Life Sciences	ADOPTION MODEL Regulatory Compliance
IMPLEMENTATION COMPLEXITY High		

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

Why it matters

- **Strengthen data protection practices** Ensure robust safeguards are in place to prevent unauthorized access, loss, or corruption of sensitive health information.
- **Support regulatory compliance** Demonstrate adherence to stringent French and EU laws, reducing legal and financial risks associated with non-compliance.
- **Enhance operational resilience** Maintain continuous availability and reliability of healthcare services by enforcing strict requirements for system stability and recovery.
- **Increase audit readiness** Streamline independent assessment processes, making it easier to demonstrate compliance during regulatory or customer audits.

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How SmartSuite supports France HDS

HDS Scope and Hosting Inventory

Define in-scope hosting services, environments, and responsibilities.

HDS Control Library and Ownership

Organize HDS requirements into controls with owners and operating cadence.

Evidence Collection and Audit Trail

Centralize policies, technical proof, and operating evidence tied to each control.

Incident Response and Continuity Testing

Manage incidents, BC/DR tests, and corrective actions with full traceability.

Access and Privilege Governance

Track privileged access, reviews, approvals, and monitoring evidence.

Certification Readiness Reporting

Report readiness, gaps, and evidence coverage for HDS audits.

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

What is France HDS used for?

France HDS (Hébergement de Données de Santé) is used to ensure the secure hosting, processing, and management of healthcare data within France. It prescribes legal and technical requirements for protecting sensitive personal health information against cyber threats, ensuring confidentiality, integrity, and availability.

Is France HDS certification mandatory?

Yes, France HDS certification is mandatory for any organization that hosts, processes, or transmits healthcare data in France. This includes both cloud service providers and on-premise hosting companies handling health-related personal data.

Who does France HDS apply to?

France HDS applies to all service providers—public or private—managing the storage, processing, or transmission of healthcare data belonging to French residents. It is relevant to healthcare organizations, IT providers, and any third-party processors engaged in healthcare data handling.

What are the key requirements of France HDS?

France HDS requires organizations to implement controls across seven domains, including physical security, logical/access controls, data confidentiality, risk management, incident response, continuity planning, and privacy governance. Compliance includes documenting practices, securing infrastructure, and establishing robust data protection measures aligned with French and EU regulations.

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How does an organization achieve France HDS certification?

Organizations must conduct risk assessments, implement prescribed technical and organizational controls, and undergo a rigorous audit by an accredited body. They must demonstrate continuous compliance through ongoing monitoring, policy documentation, and evidence of operational controls.

How does France HDS relate to other frameworks like ISO 27001?

France HDS shares similarities with ISO 27001, particularly in information security management, but it imposes additional requirements specific to healthcare data protection under French law. Many organizations choose to integrate both frameworks to achieve comprehensive compliance and risk management.

What are the ongoing compliance requirements for France HDS?

Certified organizations must conduct regular internal audits, maintain up-to-date documentation, monitor for security incidents, and report on compliance status. Continuing education, control testing, and annual reassessments are essential to maintain certification and address evolving cyber risks.

How would SmartSuite support France HDS?

SmartSuite supports France HDS management by providing integrated risk registers, centralized control management, and automated evidence collection tools. It streamlines compliance tracking, enables regulatory reporting, supports audit readiness, and facilitates workflow management for remediation and ongoing control monitoring.

License included / downloadable: Yes The HDS certification framework is published by the French Ministry of Health and supporting regulatory authorities and is publicly available through official government resources.

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