

# Order of 26 April 2024 amending the Order of 11 June 2018 approving the accreditation framework of certification bodies and the certification framework for hosting personal health data

NOR: TSSD2325104A

ELI: <https://www.legifrance.gouv.fr/eli/arrete/2024/4/26/TSSD2325104A/jo/texte>

Official Journal of the French Republic No 0113 of 16 May 2024

Text No 10

- Annex

The Minister of Economy, Finance and Industrial and Digital Sovereignty and the Minister Delegate to the Minister of Labour, Health and Solidarity, responsible for health and prevention,

Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation);

Having regard to Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, and in particular notification No 2023/0682/FR dated 5 December 2023;

Having regard to the Public Health Code, with particular reference to Articles L. 1111-8 and R. 1111-10 thereof;

Having regard to Law No 78-17 of 6 January 1978 on data processing, data files and individual liberties, as amended;

Having regard to the Order of 11 June 2018 approving the accreditation framework of certification bodies and the certification framework for hosting personal health data;

Having regard to the opinion of the National Commission on Information Technology and Liberties dated 13 July 2023,

Hereby order:

## **Article 1**

Articles 1 and 2 of the above-mentioned Order of 11 June 2018 are replaced by articles worded as follows:

“ Article 1 - The accreditation framework of certification bodies for hosting personal

health data referred to in Article R. 1111-10 of the Public Health Code as amended, annexed to this Order is approved.

“ Art. 2. - The certification framework for hosting personal health data referred to in Article R. 1111-10 of the Public Health Code as amended, annexed to this Order is approved.”

## **Article 2**

The provisions of Article 2 of the Order of 11 June 2018 referred to above, in their wording resulting from this Order, shall enter into force within 6 months of its publication. They shall apply to applications for a certificate of conformity and to applications for the renewal of such a certificate submitted to a certification body from that date.

## **Article 3**

This Order and its annexes shall be published in the Official Journal of the French Republic.

## **Annex**

ANNEXES

You can view the entire text with its images from the extract of the authenticated electronic Official Journal accessible at the bottom of the page

Done on 26 April 2024.

The Delegate Minister to the Minister of Labour, Health and Solidarity, responsible for health and prevention,

For the Minister and by delegation:

The Delegate for Digital Health,

H. Ghariani

The Minister for Economy, Finance and Industrial and Digital Sovereignty,

For and on behalf of the Minister:

The Director General of Enterprise,

T. Courbe