



Notification Number: 2017/379/F

Order approving the accreditation reference system for certification bodies and the certification reference system for hosting personal health data

Date received : 10/08/2017

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Issue of comments by : Italy

Message

Message 002

Communication from the Commission - TRIS/(2017) 02130

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2017/0379/F

No abre el plazo - Nezaahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késések - Ma' jiftaħ il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201702130.EN)

1. Structured Information Line

MSG 002 IND 2017 0379 F EN 10-08-2017 F NOTIF

2. Member State

F

3. Department Responsible

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4. Notification Number

2017/0379/F - SERV

5. Title

Order approving the accreditation reference system for certification bodies and the certification reference system for hosting personal health data

6. Products Concerned

Services for hosting personal health data collected during prevention, diagnosis, treatment or social or socio-medical monitoring

7. Notification Under Another Act

- Directive 2006/123/EC on services in the internal market
- Directive 98/48/EC Information Society services only
- requirements reserving access to particular suppliers
- Articles 1 and 2 of the draft order approve the two reference systems used within the framework for certifying hosts of personal health data:
 - the accreditation reference system for certification bodies;
 - the certification reference system.

8. Main Content

This draft order is enacted pursuant to Article R1111-10 of the Public Health Code, as amended by the Decree on the hosting of personal health data (Notification No 2017/343/F). The order approves the following:

- the reference system regarding the accreditation of certification bodies for hosting personal health data,
- the reference system regarding certification for hosting personal health data.

In accordance with point II of Article L1111-8 of the Public Health Code, persons who host personal health data collected during prevention, diagnosis, treatment or social or socio-medical monitoring, on behalf of natural or legal persons behind the production or collection of said health data or on behalf of the patients themselves, must hold a certificate of conformity.

According to Article R1111-10, this certificate must be issued (1) by a certification body accredited in accordance with the accreditation reference system drawn up by the public interest group mentioned in Article L1111-24 in conjunction with the relevant accreditation bodies and (2) on the basis of a certification reference system drawn up by the same public interest group, after consultation with the French Data Protection Authority (CNIL).

9. Brief Statement of Grounds

Given the particularly sensitive nature of health data, the aim behind the certification procedure is to ensure the host can provide sufficient guarantees regarding the safety and confidentiality of health data. The procedure is fully in line with the central concept of 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, which recommends implementing certification mechanisms.

This new certification procedure is also a well-known procedure in the world of industry. It is transparent, predictable (based on a public – and thus auditable – system of requirements) and more flexible (with a progressive reference system thanks to the implementation of a reference system life cycle), with shorter timeframes for hosts. Moreover, this new procedure makes allowances for the fact that the hosting may be carried out in a different global location (hosting service provider under international law, hosting provided outside France).

The certification is justified on account of the protection of fundamental rights recognised by the Court of Justice of the European Union as an overriding reason of general interest, specifically the respect for private life and the protection of personal data. The mechanism is implemented in order to ensure the security and confidentiality obligations of personal data hosts, in particular pursuant to the provisions of Law 78-17 of 6 January 1978 on data processing, data files and individual liberties, as amended, and in broader terms pursuant to the aforementioned Regulation (EU) 2016/679 on the protection of personal data. This certification is also laid down in order to provide natural persons with assurances regarding respect for their private life and medical confidentiality. It will help reduce the risk of personal data being compromised by applying stricter conditions for hosting said data.

In conclusion, this certification is suitable, necessary and proportionate in terms of the intended goal, since it applies only to hosts of personal health data collected during prevention, diagnosis, treatment or social or socio-medical monitoring – data that is particularly sensitive and key to individuals' privacy.

10. Reference Documents - Basic Texts

Reference(s) to basic text(s): - Order No 2017-27 of 12 January 2017 on the hosting of personal health data;

- Draft Decree on the hosting of personal health data. (Notification No 2017/343/F)

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

-

13. Confidentiality

No

14. Fiscal measures

No

15. Impact assessment

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16. TBT and SPS aspects

TBT aspect

No - the draft has no significant impact on international trade.

SPS aspect

No - the draft is neither a sanitary nor phytosanitary measure.

European Commission

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