EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

Notification Number: 2020/315/F

Draft Order of 20 May 2020 supplementing the Order of 23 March 2020 prescribing the organisational and operational health system measures necessary to deal with the COVID-19 epidemic in the context of the state of health emergency

Date received : 20/05/2020

End of Standstill :

Message

Message 002

Communication from the Commission - TRIS/(2020) 01786
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2020/0315/F

No abre el plazo - Nezahajuje 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 késéseket - Ma' jiftaħx 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 - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 202001786.EN)

1. Structured Information Line
MSG 002 IND 2020 0315 F EN 20-05-2020 F NOTIF

2. Member State
F

3. Department Responsible
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4. Notification Number
2020/0315/F - S10S

5. Title
Draft Order of 20 May 2020 supplementing the Order of 23 March 2020 prescribing the organisational and operational health system measures necessary to deal with the COVID-19 epidemic in the context of the state of health emergency

6. Products Concerned
In vitro diagnostic medical devices

7. Notification Under Another Act
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8. Main Content
In particular, the draft text provides that:

- in vitro diagnostic medical devices detecting antibodies against SARS-CoV-2 through serological testing are subject to an evaluation procedure;
- any natural or legal person engaged in the manufacture, placing on the market, distribution or import of such devices must make a declaration to the National Agency for the Safety of Medicines and Health Products [Agence nationale de sécurité du médicaments et des produits de santé – ANSM];
- such a declaration must include the declaration of CE conformity and/or the product leaflet;
- in vitro diagnostic medical devices are evaluated by the National Reference Centre for Respiratory Viruses;
- after verification by the ANSM of the documents accompanying the declaration, and on the basis of scientific evaluations carried out by the National Centre, a list of in vitro diagnostic medical devices conforming to the standards set by the National Authority for Health is established;
- only in vitro diagnostic medical devices on this list may be purchased and used by clinical laboratories.

9. Brief Statement of Grounds
The World Health Organization (WHO) declared that the emergence of a novel coronavirus (COVID-19) constitutes a public health emergency of international concern on 30 January 2020.

There are still predicted constraints on the supply of in vitro diagnostic medical devices. The European Commission also strongly recommends carrying out additional validation of the clinical performance of the tests to detect antibodies against SARS-CoV-2, carried out by the competent authorities and reference laboratories in the Member States. It is therefore necessary to introduce such validation.

10. Reference Documents - Basic Texts
Reference(s) to basic text(s): Article L3131-16 of the Public Health Code

11. Invocation of the Emergency Procedure
Yes

12. Grounds for the Emergency
Emergency measure to protect the population against the serious health threat posed by the COVID-19 novel coronavirus.

13. Confidentiality
No

14. Fiscal measures
No

15. Impact assessment
-

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.

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European Commission

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