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Subject: Withdrawal of the United Kingdom and national derogations from the conformity assessment procedures for medical devices

This information is addressed to the EU27 Competent Authorities for Medical Devices to facilitate consistency among possible national derogations concerning conformity assessment of medical devices that have been previously certified by UK notified bodies[1].

On 29 March 2017, the United Kingdom submitted the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union (TEU). On 22 March 2019, the European Council adopted Decision (EU) 2019/4761 extending the period under Article 50(3) TEU in agreement with the United Kingdom. In accordance with that Decision, in the event that the Withdrawal Agreement is not approved by the House of Commons by 29 March 2019 at the latest, the period provided for in Article 50(3) TEU is extended until 12 April 2019. As the Withdrawal Agreement has not been approved by 29 March 2019, Union law will cease to apply to and in the United Kingdom from 13 April 2019 ("the withdrawal date").

The European Commission informed economic operators and Notified Bodies working in the medical device sector in early 2018 about the impact of the United Kingdom's withdrawal and the need to adapt their status and the status of their certificates in order to ensure their continuous validity and exploitation, once the United Kingdom has left the Union[2]. This should have contributed to a high level of preparedness of the sector.

In particular, Union product legislation[3] requires Notified Bodies to be designated by a Member State notifying authority for performing the conformity assessment tasks set out in the relevant act of Union product legislation.

As of the withdrawal date, a medical device can no longer be placed on the EU-27 market on the basis of a certificate issued by a UK notified body. However, as clarified in the Commission's "Question and Answers" document published in February 2019[4], the individual product already placed on the EU27 market can continue to be made available, i.e. supplied in the distribution chain. Moreover, the possibility to *use* a medical device by health professionals or the patient/consumer is not affected by EU law on medical devices.

While the transfer of certificates issued by UK Notified Bodies to EU27 Notified Bodies is steadily progressing, several Member States have expressed the concern that there may be

1 Including *in vitro* diagnostics medical devices and active implantable medical devices.
2 See the "Notice to stakeholders" published in January 2018 (https://ec.europa.eu/info/sites/info/files/file_import/industrial_products_en_1.pdf), and the "Questions and answers" document published in February 2019 (https://ec.europa.eu/info/sites/info/files/qa_brexit_industrial_products_en.pdf).
3 Under Medical Device Directives: Article 11 of Directive 90/385/EEC, Article 16 of Directive 93/42/EEC and Article 15 of Directive 98/79/EC.
4 https://ec.europa.eu/info/sites/info/files/qa_brexit_industrial_products_en.pdf

objective reasons beyond the control of a manufacturer (or his/her EU27 authorised representative) that may prevent the timely transfer of a certificate to the EU27 by the withdrawal date. They have called on the Commission to provide guidance in order to ensure that this would not lead to a shortage of critical devices in the EU and to coordinate the measures that would be taken at national level. The purpose of the present letter is to provide such guidance.

Legal basis for temporary national derogations from the conformity assessment procedures for medical devices

Article 9(9) of Directive 90/385/EEC, Article 11(13) of Directive 93/42/EEC and Article 9(12) of Directive 98/79/EC provide that competent authorities may authorise, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the certificate of conformity has not been issued by an EU27 Notified Body and the use of which is in the interest of protection of health.

In the context of a no deal Brexit, a request would be duly justified if the following conditions are met:

1. The manufacturer (or his/her EU27 authorised representative) holds a certificate issued by a UK Notified Body that could not yet be transferred to a EU27 Notified Body;
2. The individual medical device(s)[5] is of critical importance for the protection of health;
3. There is a lack of suitable substitutes available;
4. The derogation sought is temporary and the period of validity in principle does not go beyond 31 December 2019.

In order for the competent authorities to assess whether the conditions set out above are met, the affected manufacturer (or his/her EU27 authorised representative) or a health institution must submit, with the request to the competent authority of the Member State, the following information:

- A manufacturer (or his/her EU27 authorised representative) should refer to a certificate issued by a UK Notified Body, explain the reasons why it could not be transferred to an EU27 Notified Body prior to the withdrawal of the United Kingdom, and demonstrate the criticality of the medical device;
- A health institution should explain the criticality of the medical device for which a derogation is sought and the reason why it cannot be substituted.

The competent authority shall assess the request for authorisation. If the competent authority considers that the request is justified, it shall authorise the medical device for the period strictly necessary and for the specified device(s).

Coordination of national measures

In order to ensure the continued functioning of the Single Market, and a coherent approach by Member States, the European Commission will monitor, coordinate and ensure the transparency of the use Member States make of the derogations. To this avail, it will put at the disposal a central repository[6] allowing Member States competent authorities to share with each other the authorisations they have granted.

[e-signed]
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[5] Devices are specified, for instance, by a reference to a certificate number issued by the UK Notified Body and/or any particular category of device covered by that certificate.

[6] https://circabc.europa.eu/ui/group/8656a610-a938-4c44-b1a0-f473320b1928