fieldfisher

Stop Press:

Medical device manufacturers' **emergency preparation for Brexit**

If you are a manufacturer of medical devices which you sell into the European Union (EU) and your notified body for EC Certificates of Conformity is still in the UK, and you want to sell your devices in EU27:

You need to act now!

Explanation

The UK Parliament has failed to pass legislation accepting the agreement made by the UK Prime Minister with the EU. We have no idea if this legislation will ever be passed by parliament. This means that the transition period included in that agreement will most likely not be available. The UK is also more likely to exit the EU without an agreement, the so called "hard Brexit". For now, you should therefore assume that from 30th March 2019, EC Certificates of Conformity issued by UK notified bodies will no longer be valid, except for products placed on the market solely in the UK.

In this event, products covered by UK notified body-issued EC Certificates of Conformity will not be able to be lawfully sold in the EU27 on or after 30 March 2019.

UK Notified Bodies: Action depends on your UK notified body

BSI UK: BSI has opened a Netherlands operation which is separately authorised to provide EC Certificates of Conformity under the medical device directives. BSI has provided a process for "migration" of certificates from the UK to the Netherlands which is a much shorter and quicker process than is usual for a transfer between notified bodies. However, because of a backlog, this process is becoming longer than originally envisaged. Device companies with a number of devices are also finding the process more arduous.
Action: For BSI UK Certificates, obtain your information pack from BSI by request to: CECert2NLNB@bsigroup.com and make your application for migration as soon as possible.

LRQA: LRQA have similarly established a branch in the Netherlands. However, they are due their assessment in mid-March and will not be authorised until some point between June and September: too late in case of a hard Brexit from 30th March. **Action: See next page.**

SGS: SGS has notified bodies registered in Finland and Belgium, but have not issued any specific migration process in the form that BSI has (and which was expressly agreed with the EU Commission). Anyone now applying to transfer their CE Certificates of Conformity to SGS in either Finland or Belgium are being told that will not receive new certificates before 30 March 2019: too late in case of a hard Brexit from 30th March. **Action: See next page.**

UL International (UK) LTD: UL International is currently only registered in the UK for EC Certificates of Conformity for medical devices and IVDs. Manufacturers with EC Certificates of Conformity will need to transfer to another notified body in EU27, but as this is likely to occur: too late in case of a hard Brexit from 30th March. **Action: See next page.**

Actions

1. Immediate Action if UK NB is LRQA, SGS or UK International

Unfortunately, if your EC Certificates of Conformity have been issued by LRQA, SGS or UL International and you have not yet taken steps to obtain certificates from an alternative notified body, you are unlikely to obtain new certificates in time. We can only suggest steps which might help reduce the length of time that your devices are without EC Conformity Certificates for the EU27. We also have some thoughts on other mitigation steps which might at least for some companies offer a stop-gap.

Steps to New EC Conformity Certificates from EU27 notified body

Find a new notified body – ask all notified bodies authorised to provide certificates for your devices on their availability and likely timings for the transfer, and select the one you consider will provide an efficient service (timings should be in a written agreement). Use this link to the database and then click the link for the directive applicable to your devices and check the list of the type of devices each is authorised to certify: http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.main.

Take the prescribed steps for a transfer, which will involve providing all information on the certificates issued to date.

2. Stop-Gap: Fieldfisher's specialist medical device regulatory team can help you!

i. Apply for a "grace period": The grace period is not EU law, and therefore is in the gift of individual countries. The Netherlands, France and Switzerland have written guidance or laws for these extensions and they are also provided in Germany. The grace period was agreed by the European Commission's Competent Authorities for Medical Devices group for the purpose of manufacturers whose notified bodies close down. In this case we would ask the competent authority to apply the grace period by analogy to the Brexit situation where the UK notified body can no longer provide valid certificates – this is yet to be tested.

Note:

- Apply to the competent authority in the country in which the manufacturer has their registered address, or, if outside the EU27, where the manufacturer's authorised representative has their registered address;
- If granted, the grace period is valid for the EEA, plus Switzerland and Turkey;
- A grace period can be granted for up to 12 months (from 30 March 2019 in this case);
- Expect to have conditions placed on the manufacturer such as providing regular updates on vigilance, sales figures and/ or progress to the new certificates.

ii. If a grace period is not available, apply for derogations: Unlike the grace period, derogations are provided for by law in each of the Directives. However, they have to be applied for country-by-country and are valid only for sales of specified products in the applicable country. They are not available in Switzerland. The provisions require that derogation is granted for the "protection of health" and this is very differently applied. In some countries it is sufficient for devices to be in shorter supply for very sick patients or emergency situations. Some countries require that the hospitals supply a written request justifying the need. Expect conditions to attach to the derogations and for them to be granted for much shorter period.