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MHRA GUIDANCE – CE-MARKED MEDICAL DEVICE REGISTRATION IN THE UK IN THE CASE OF NO BREXIT DEAL

On 4th January 2019 the MHRA (the English Competent Authority) published a guidance note, to provide further information to manufacturers of healthcare products (including medical devices) in case there is no Brexit deal agreed by March 29th, 2019.

Until now, the notification of placing on the market of CE-marked medical devices in the UK was mandatory only for class I medical devices, system and procedure packs, custom-made medical devices, and only in the case where the manufacturer or his Authorised Representative was located in the UK.

In its recent guidance note MHRA has stated that **after March 29th, 2019, in the event of no Brexit deal, all medical devices, active implantable medical devices, in-vitro diagnostic medical devices and custom-made medical devices will need to be registered with the MHRA prior to being placed on the UK market**.

Given the uncertainty over the Brexit arrangements, MHRA has defined timelines for the registration of medical devices post a no deal Brexit.

Delay after March 29th, 2019	Medical devices to be registered
4 months	- Class III medical devices - Class IIb implantable medical devices - Active implantable medical devices - IVD List A
8 months	- Class IIb non-implantable medical devices - Class IIa medical devices - IVD List B - Self-test IVDs
12 months	- Class I medical devices - Self-certified IVDs - Class A IVDs

Registration for custom-made devices will be in line with the risk classification of the device.

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Where a medical device manufacturer is not established in the UK, the registration of a device with the MHRA must be undertaken by a **"UK Responsible Person" established in the UK and with a UK registered address** who will take the responsibility for the device in the UK. MedPass can assist in this regard. Please note that it will not be necessary to mention this "UK Responsible Person" on the medical device labelling.

This guidance note is also applicable if your CE-marked medical device is used in the UK in the context of a post-market clinical investigation.

This MHRA guidance note is only applicable in case of no Brexit deal and we can only advise you to be prepared for these registrations in such circumstances.

MedPass can offer support both with the registrations and the 'UK Responsible Person' so please do not hesitate to contact for any additional information you may need.

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