intertek
Total Quality. Assured.

SUMMARY OF KEY REQUIREMENTS FOR PLACING A DEVICE ON THE GREAT BRITAIN MARKET FROM 1 JANUARY 2021

MHRA published their guidance document **"Regulating medical devices from 1 January 2021"** on the 1st of September 2020: https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021

From 1 January 2021, there will be a number of changes to how medical devices are placed on the market in Great Britain. These are:

- Certificates issued by European Economic Area (EEA)-based Notified Bodies will continue to be valid for the Great Britain and Northern Ireland (NI) market (see special rules and guidance NI market – links below) until 30 June 2023

  https://www.gov.uk/government/publications/moving-goods-under-the-northern-ireland-protocol/moving-goods-under-the-northern-ireland-protocol-section-two-moving-goods-from-great-britain-to-northern-ireland#great-britain-to-northern-ireland-manufactured-goods

  https://www.gov.uk/government/publications/moving-goods-under-the-northern-ireland-protocol/moving-goods-under-the-northern-ireland-protocol-introduction#northern-ireland-tofrom-the-eu

- A new route to market and product marking will be available for manufacturers wishing to place a device on the Great Britain market from 1 January 2021.
- From 1 January 2021, all medical devices, including in vitro diagnostic medical devices (IVDs), placed on the UK market will need to be registered with the MHRA. There will be a grace period for registering:
  - Four (4) months for Class IIIs and Class IIb implantable, and all active implantable medical devices
  - Eight (8) months for other Class IIb and all Class IIa devices
  - twelve (12) months for Class I devices
  - The above twelve (12) month grace period will not apply to manufacturers of Class I devices and general IVDs that are currently required to register with the MHRA.
- The above twelve (12) month grace period will not apply to manufacturers of Class I devices that are currently required to register with the MHRA.
- Registration for custom-made devices will be in line with the risk class of the device.
- Class I devices, custom-made devices and general IVDs being placed on the Northern Ireland market must continue to register as normal as the twelve (12) month grace period will not apply.
- From 1 January 2021, the roles and responsibilities of those manufacturing and supplying medical devices and IVDs will change, manufacturers wishing to place a device on the UK market will first need to register with the MHRA.

If you are a manufacturer based outside the UK and wish to place a device on the UK market, you will need to establish a UK Responsible Person who will take responsibility for the product in the UK.

The proposals outlined by MHRA will take effect through legislative changes that will be introduced later in 2020. They are still therefore subject to parliamentary approval, and therefore change.

On confirmation from MHRA of the new proposed route to market yet to be announced in 2020, once known, Intertek will provide the necessary resources to assist your market access as seamless as possible.

To assess our client's UK medical certification needs, Intertek requests your support in supplying scope background data. Please supply us with both a list of devices that you are currently selling, or those intend to sell, and identify which of these you intend to continue to market in the United Kingdom.

We kindly ask you to reply by 5th of October 2020 by email medtechsweden@intertek.com and information will be kept confidential.