From: nss iric
Sent: 15 September 2020 17:39
Subject: Information Message IM/2020/022 - Regulation of medical devices and in-vitro diagnostic medical devices

IRIC Incident Reporting & Investigation Centre

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Subject: Regulation of medical devices and in-vitro diagnostic medical devices

This information message is sent to draw the attention of Equipment Co-ordinators to information which may be relevant to the safety of equipment and facilities in NHS Boards and Local Authorities. Please find the information below.

From 1 January 2021, there will be a number of changes to the way that medical devices and in-vitro diagnostic medical devices (IVDRs) are regulated in Great Britain (GB). These include:

- The CE mark will continue to be used and recognised until 30 June 2023
- Certificates of conformity issued by European Economic Area (EEA)-based Notified Bodies will continue to be valid for the GB market until 30 June 2023
- Manufacturers wishing to place a device on the GB market from 1 January 2021 will have a new route to market and a new product marking to replace the CE mark.
- UK Conformity Assessment (UKCA): from 1 January 2021, all medical devices and in vitro diagnostic medical devices (IVDs) placed on the UK market will need to be registered with the MHRA. Manufacturers will be given a grace period for registering:
  - Four months for Class IIIs and Class IIb implantables, and all active implantable medical devices
  - Eight months for other Class IIb and all Class IIa devices
  - Twelve months for Class I devices
- The 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.
- Manufacturers which are based outside the UK and wish to place a device on the UK market, will need to establish a UK Responsible Person who will take responsibility for the product in the UK.

MHRA has produced more detailed information which you can access here:

https://www.gov.uk/government/collections/mhra-post-transition-period-information

IRIC is working with Scottish Government to share information on these changes with the Equipment Co-ordinator network. Please look out for more information messages and ensure you attend Equipment Co-ordinator meetings or nominate a deputy if you can't attend yourself.

As the Equipment Co-ordinator for your organisation, we recommend that you assess whether or not to forward this information to managers and staff within your area of responsibility who might benefit from being aware of it.

If you received this message directly from IRIC, email us at nss.iric@nhs.scot or phone 0131 275 7575 quoting the IM reference number. Alternatively, if you have received this message from someone in your own organisation, please direct all enquiries to them and they will liaise with IRIC as required.

Incident Reporting & Investigation Centre (IRIC)
Health Facilities Scotland
NHS National Services Scotland

Contact us:
IRIC Email nss.iric@nhs.scot
Helpline 0131 275 7575

https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/report-an-incident/

FAC406-210 Rev 1