

Medical Device Alert

Action update

Ref: MDA/2010/001 Issued: 04 January 2010 at 11:00

Device

Medical devices in general and non-medical products.

Problem

- Off-label use of medical devices.
- User modifications of devices other than directed by the device manufacturer.
- Use of products, other than those that are CE-marked as medical devices, for clinical purposes.

Action

Ensure users are aware of the risks associated with and, where possible, avoid:

- the off-label use of medical devices
- the modification of medical devices (unless such modifications are sanctioned in the manufacturer's instructions for use)
- the use of products other than those CE-marked as medical devices in clinical settings, particularly when CE-marked medical devices that are specifically designed and manufactured to be used for that clinical purpose are available.

Action by

All staff involved in the use of medical devices.

CAS deadlines

Action underway: 05 March 2010
Action complete: 05 May 2010

Contact

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