

Non-Compliant and Counterfeit Medical Devices

Non-Compliant and Counterfeit Medical Technology Devices can injure patients, and significantly endanger a Company's reputation and business. Here Alan Birks of AXREM examines the dangers and what you can do about it.

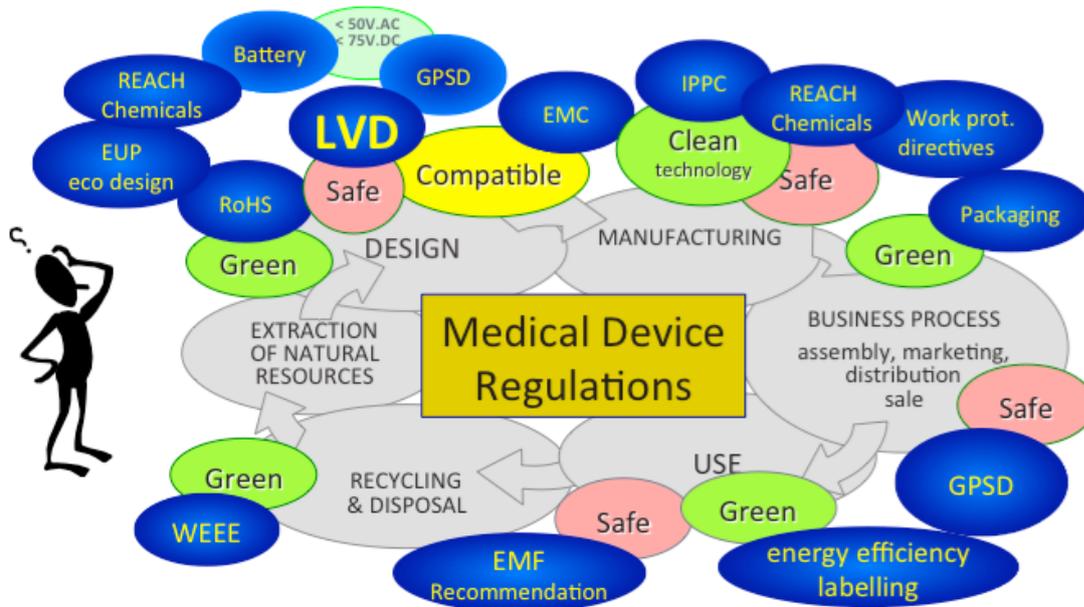
Whilst sitting on the beach in some sunny clime we have probably all no doubt witnessed the annoying presence of the "knock off" watch, phone charger or handbag salesmen. While they may be irritating, we probably give little thought to the impact that these individuals are having on the original brands. Indeed, you might even make a purchase, accepting the fact that the product may not last long or operate correctly.

However, when back at the day job, it's worth thinking what the impact would be if you were passively complicit in allowing Non Compliant and Counterfeit Medical Technology Devices into the medical arena with the potential for death or injury caused by the failure of such devices.

It goes without saying that in the Healthcare sector it is imperative that we keep fraudulent counterfeits out of our market. It is equally vital that all Medical Technology Devices comply with the relevant standards and regulations. Non-compliant devices and spare parts can also be dangerous and result in mis-diagnosis or adversely affect the patient care pathway if they do not meet the specification of the original equipment manufacturers specification, including the requirements of the appropriate standards and regulations, which include the Medical Device Regulations.

Market surveillance, which is part of the Medical Device Regulations, is essential to ensure that devices on sale in the EU comply with existing legislation and remain safe throughout their life. This ensures patients are protected from potential harm that defects and fraudulent devices could cause.

Compliance with all the legal and regulatory requirements has become very complex, but legitimate manufacturers will take care of these requirements for their products. However, the end user (customer) has an important part to play in ensuring the ongoing obligations are met. This includes reporting adverse reactions and defects along with ensuring medical devices are operated and maintained in line with the manufacturer's instructions.



So, what is Counterfeit and what is Non-Compliance?

Modified, Sub-standard, Dodgy, Defective, Unsafe, Counterfeit, Non Approved, Non Compliant, Fake, Illegal and Non-Certified are some of the terms that will generally fall into one, or both, of the following definitions:

- The device carries **false or misleading claims** in respect of its performance, compliance with legislation or fitness for purpose
- The device **infringes** the Intellectual Property (IP) rights of the registered owner.

If a device carries markings of the appropriate standard and is CE marked but these are false claims, **then this device falls into the Non-compliant, sub-standard, non-conforming category** If a device carries a brand name or trademark that is owned by someone else, **then this is theft of IP and the device falls into the counterfeit, fake and illegal category** It usually follows that a counterfeit device will also be non-compliant. In all cases these devices are likely to be sub-standard, dangerous, and defective.

How can devices supplied by AXREM members be affected?

All diagnostic medical imaging and radiotherapy equipment installed in UK hospitals is required to comply with the requirements of the Medical Device Regulations. Manufacturers invest considerable financial and manpower resources to ensure that

their equipment is developed and manufactured in accordance with these regulations. However, it is vitally important that medical equipment is correctly maintained and serviced, since failure to do so opens up an opportunity for non-compliant, modified or counterfeit components to be installed when replacement parts are required. Fitting non-compliant, modified or counterfeit components would invalidate the compliance of the equipment; as would the installation or servicing of equipment or devices not in accordance with the original manufacturer's requirements.

What are your responsibilities?

Service and maintenance needs to be undertaken by competent personnel and in accordance with the original equipment manufacturer's instructions, using parts meeting the original manufacturer's specification. Selling, procuring or installing non-compliant, modified or counterfeit parts and devices has consequences if equipment fails or operates incorrectly, including:

- Compromised diagnostic or therapeutic performance impacting on patient care pathways
- Poor performance and/or reliability problems
- Damage to equipment and infrastructure
- Inconvenience from loss of service
- Possible detrimental or safety effects on other nearby Medical Devices
- Additional cost, such as loss of service or device replacement upon failure
- Damage to reputation
- Injury or death of patient and users
- Criminal proceedings, fines or imprisonment

How can you avoid the risks?

Procurement teams should:

- Establish and maintain robust procurement processes to minimise the risk of buying non-compliant and counterfeit parts and devices
- Not be afraid to check out any supplier's approvals/marks/registrations
- Confirm those repairing and servicing medical equipment are doing so in accordance with the manufacturer's instructions and using approved parts to prevent invalidating the CE marking of the device.
- Establish an audit process to test your ability to avoid buying these non-compliant or counterfeit parts and devices

Unrestricted



- Maintain good, auditable records for traceability
- Work with known devices, trusted brands and reliable supply chain sources
- Be extra cautious when considering buying unknown devices and/or through unfamiliar channels/sources
- Where a maintenance contract is procured that includes the provision of spare parts, be sure to check that the provenance of the spare parts source is of the appropriate standard; never just assume
- Ensure personnel (at ALL levels) are trained to be aware of the risks and consequences.

Where can you go for further help?

If you are unsure of the validity of parts you are considering fitting to medical equipment then contact the original equipment manufacturer’s that can advise if this would invalidate the compliance of the equipment.

The AXREM Trade Association and its members work closely with the Medicines and Healthcare Products Regulatory Agency (MHRA) who have processes in place to monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for patients and users. It is required that all incidents and adverse reactions are reported to the MHRA where harm or potential harm has occurred. The original equipment manufacturers should also be informed of any incidents and adverse reactions and, as part of their surveillance duties under the medical device regulations, they have a responsibility to advise the MHRA accordingly.

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AXREM is the trade association representing the suppliers of diagnostic medical imaging, radiotherapy, healthcare IT and care equipment in the UK. AXREM members supply most of the diagnostic medical imaging and radiotherapy equipment installed in UK hospitals. In doing so, our member companies and their employees work side by side with Consultant Radiologists, Radiographers and Practitioners, Oncologists and a wide range of healthcare professionals in delivering healthcare to patients using our technologies. Our members therefore have unique knowledge, experience and insight into the workflow and challenges faced by healthcare professionals on a day-to-day basis, which enables us to develop and offer innovative solutions to improve the speed and quality of diagnostic procedures and treatments with the ultimate aim of improving patient care.

For additional information about AXREM, call 020 7642 8087, email alan.birks@axrem.org.uk or visit www.axrem.org.uk