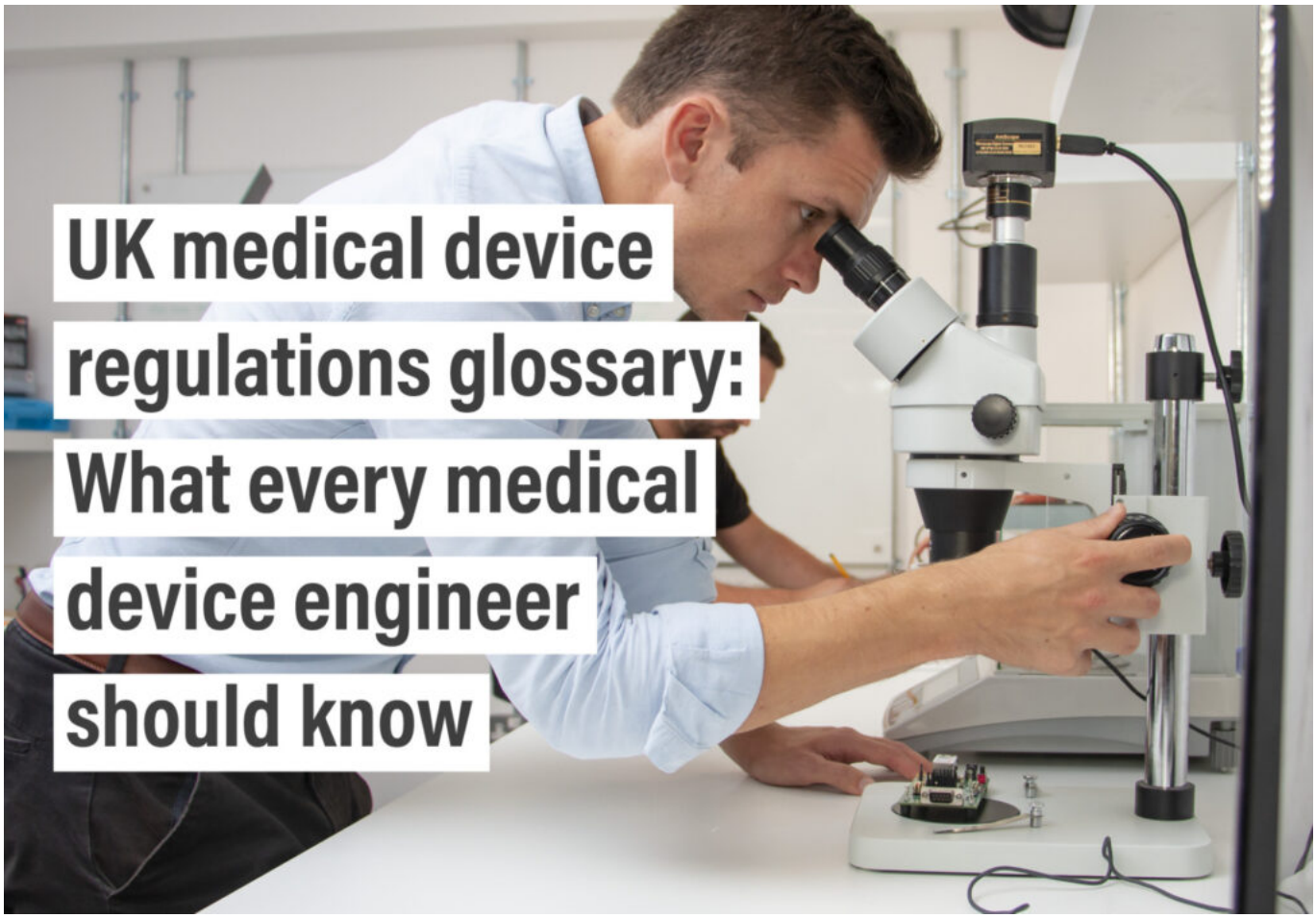
UK medical device regulations glossary: What every medical device engineer should know



UK Medical Device Regulations (MDR) Glossary: What every medical device engineer should know

Reading time 12 mins

Key Points

- As demand for healthcare technologies increases, rushing to get products to the market by cutting corners can have serious consequences
- UK medical device regulations (UK MDR) exist to ensure that products are safe, efficient and compliant; but also to avoid worst-case scenario of product recalls
- The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating the UK medical devices market. Each country (e.g. USA) and region (e.g. Europe) has its own regulatory body that medical device engineers should comply with in accordance to the market in which their product will be placed
- Navigating regulations, directives, standards, and conformity assessments can be challenging
- A list of key terminology that medical device engineers and quality managers should know is helpful to having a strong foundation from which to develop medical devices

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Digital Healthcare is one of the fastest-growing markets globally. As increased demand for healthcare technologies fuels investor excitement, companies that rush to get their products to market to gain a competitive edge by cutting corners (e.g. inadequate testing) risk having those products recalled at a later stage. Product recall is any developer or medical device engineer's worst nightmare. Not only can this lead to significant financial and reputational losses, but in the worst-case scenario: injury or loss of life. UK medical device regulations (UK MDR) exist to ensure that the products we design are safe, efficient, effective, and of the highest quality, thereby avoiding worst-case scenarios.

At the same time, these regulations – which can differ from one country/region to the next – can be a minefield to navigate. Below is a glossary of core medical device regulations (MDR) every engineer or quality control manager should know. It's not an extensive list, but it's comprehensive and should help you build a solid foundation from which to develop your medical device or product.

Regulatory bodies for medical devices

REGION	REGULATORY BODY	ACRONYM	ROLE
United Kingdom	Medicines and Healthcare products Regulatory Agency	MHRA	Responsible for regulating the UK medical devices market
Europe	European Medicines Agency	EMA	Evaluates the quality, safety, and performance of medical devices in relation to their use with a medicinal product
	Medical Device Regulation	EU MDR	Ensure a high standard of safety and quality for medical devices that are produced in, or supplied to, member countries of the European Union
	In Vitro Diagnostic Device Regulation	EU IVDR	Regulations for manufacturers, importers, distributors, or quality management professionals involved with in vitro diagnostic devices

USA	Food & Drug Administration	FDA	Regulates the sale of medical device products (including diagnostic tests) in the U.S. and monitors the safety of all regulated medical products
International	International Medical Device Regulators Forum	IMDRF	Medical device regulators from around the world who harmonise the regulatory requirements for medical products that vary from country to country

UK Medical Device Regulations Terminology

Please note that the terms and definitions listed below relate mostly to UK medical device regulations. Although most are also common EU medical device terminology , some may differ from one country to the next.

TERM	ACRONYM	DEFINITION
Active Implantable Medical Device	AIMD	Any active medical device intended to be introduced into the human body for diagnostic or therapeutic purposes and which is intended to remain in place, e.g. pacemakers or defibrillators
Adverse incident/event		An event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons
Artificial Intelligence as a Medical Device	AIaMD	Devices employed to fulfill human capabilities in a variety of roles with deep learning techniques using neural networks, e.g. disease prevention and diagnosis
Auditing Organisations	AOs	The bodies that carry out Medical Device Single Audit Program (MDSAP) assessments

Conformité Européenne	CE	Stamp proving that products sold have been assessed to meet high safety, health, and environmental protection requirements
Certificate of Conformity		Show that the device complies with the UK medical devices regulations
Classification		General medical devices are classified into four classes of increasing levels of risk: Class I, IIa, IIb or III in accordance with criteria in the UK medical devices regulations
Clinical Evaluation Plan	CEP	The collection of clinical data and clinical evaluation results that demonstrate safety and performance
Corrective and Preventive Actions	CAPA	Clearly documented procedures for corrective and preventive action as part of an overall Quality Management System
Custom Made Medical Device		Manufactured strictly in accordance with a written prescription and intended for the sole use of a particular person
Declaration of Conformity	DoC	A declaration that the device complies with the UK medical devices regulations
Directive 90/385/EEC on medical devices	EU MDD	Regards any medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure
Directive 90/79/EC on active implantable medical devices	EU AIMDD	Regards any active medical device that relies on electrical energy or a power source other than that directly generated by the human body or gravity
Directive 98/79/EC on in vitro diagnostic medical devices	EU IVDD	Regards testing devices used on biological samples (such as tissues, blood or urine) to determine the status of a person’s health (e.g. pregnancy)

Domestic assurance		The process through which UK Approved Bodies can perform an abridged assessment of a device with appropriate levels of scrutiny to ensure that it meets the requirements of the UK medical devices regulations, as well as an assessment of the manufacturers
EU Notified Bodies		Organisations designated by EU member states to assess the conformity of certain products before being placed on the market
Field safety corrective action	FSCA	An action by a manufacturer to reduce the risk of death or serious deterioration in the state of health associated with the use of a medical device, i.e. can be a device recall, modification, retrofit or design change, or device destruction
Global Medical Devices Nomenclature	GMDN	A list of generic names used to identify all medical devices
Grandfathering		A legacy medical device that was already on the market before an applicable directive or regulation
Health Institution Exemption	HIE	An exemption from all the requirements of the UK medical devices regulations that applies to medical devices and in vitro diagnostic medical devices (IVDs) that are used in the same health institution in which they are manufactured
Instructions for use	IFUs	The information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken
International Electrotechnical Commission	IEC	Prepares and publishes international standards for all electrical, electronic and related technologies
	IEC 62304	The set of processes, activities, and tasks described in this standard establishes a common framework for medical device software life cycle processes
	IEC 60601-1	Applicable to embedded software in a hardware medical device

	IEC 82304-1	Applicable to standalone software, also known as Software as a Medical Device (SaMD)
	IEC 81001-5-1	Requirements regarding cybersecurity
	IEC 62366-1	Requirements regarding man-machine interface ergonomics
International Organisation for Standardization	ISO	A worldwide federation of national standards bodies
	ISO 13485	Requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements
	ISO 14971	Process for risk management of medical devices, including software as a medical device and in vitro diagnostic medical devices.
Medical Device		A piece of equipment that comes into direct contact with the patient and is used to treat or diagnose a clinical condition
Medical Device Single Audit Programme	MDSAP	A route to market that would allow a single regulatory audit of a medical device manufacturer's Quality Management System (QMS) that would meet the requirements of multiple regulatory jurisdictions
Medicinal Product		A substance or combination of substances intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action

Post-market surveillance		All activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service to identify any need to immediately apply any necessary corrective or preventive actions
Quality Management System	QMS	A system intended to ensure that manufacturers consistently design, produce, and place onto the market medical devices that are safe and fit for their intended purpose
Risk Management System	RMS	Involves the identification, understanding, control, and hazard prevention during device use
Serious adverse incident/event		Critical device-related adverse incidents (e.g. device malfunction, deterioration in device performance, inadequate instructions) that may or may not result in death or serious injury
Software as a Medical Device	SaMD	Standalone software and apps that meet the definition of a medical device (including AI as a medical device (AIaMD))
UK Approved Bodies		Previously known as ‘notified bodies’, UK Approved Bodies are used where third-party conformity assessment is required to place products on the Great Britain market (England, Scotland, Wales)
UK Conformity Assessed	UKCA	A UK product marking used for certain goods, including medical devices, being placed on the Great Britain market (England, Wales and Scotland)
Unique Device Identifier	UDI	A series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard

Yellow Card Scheme		The UK system for collecting and monitoring information on safety concerns, such as suspected side effects or adverse incidents involving medicines and medical devices

Final regulatory advice for medical device engineers

If you found this post on UK medical device regulations helpful, we suggest you read our related posts on medical design tips for engineers and how to consider human factors for user-centered design.

In our next series of posts, we'll take a more detailed look into regulatory factors and proposed reforms impacting the digital healthcare industry. Please let us know if you have any questions: we can't guarantee we'll have all the answers, but we'll help you find them.

Comments

1. FINAL Consultation Medical Devices Regulations. (n.d.). GOV.UK. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1018219/Glossary_PDF.pdf
2. [Glossary] EU MDR and IVDR: The core terms you should know. (n.d.). SoftGroup. Retrieved 30 November 2022, from https://www.softgroup.eu/2020/10/19/eu-mdr-and-ivdr-glossary/
3. Medical devices regulation and safety: detailed information. (n.d.). GOV.UK. Retrieved 30 November 2022, from https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety
4. Michaud, C. (2011, November 1). ISO and IEC standards for software in medical devices in a nutshell – Software in Medical Devices, by MD101 Consulting. Property of Cyrille Michaud CC-BY-ND License. https://blog.cm-dm.com/post/2011/11/01/ISO-and-IEC-standards-explained-to-software-engineers-and-quality-managers

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