Glossary

Please note that this glossary is a tool to assist respondents with their understanding of the consultation document, which includes technical language and terminology. While some of the definitions below are set out in domestic legislation, in some cases these definitions are set out in guidance or are the MHRA's interpretation of these terms.

Term	Definition
Active Implantable Medical Device (AIMD)	A medical device which— (a) relies for its functioning on a source of electrical energy or a source of power other than that generated directly by the human body or by gravity; and (b) is intended to be totally or partially introduced into the human body (whether surgically or medically, including being introduced into a natural orifice) and which is intended to remain in the human body after completion of the surgical or medical procedure during which it is introduced, even if it is intended to administer a medicinal product or incorporates as an integral part a substance which, if used separately, would be a medicinal product
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.
Aesthetic product	A product which is similar to a medical device in terms of functioning and risk profile, but which does not have an intended medical purpose
AIaMD	Artificial Intelligence as a Medical Device
Ancillary	Provides supportive action
Approved Body	An organisation that has been designated by the MHRA to assess whether manufacturers and their medical devices meet the requirements set out in the UK medical devices regulations 2002
Auditing Organisations (AOs)	The bodies that carry out Medical Device Single Audit Program (MDSAP) assessments
Basic UDI-DI	The main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics
CE marking	A conformity marking consisting of the initials "CE"
Certificate of Conformity	A certificate to show that the device complies with the UK medical devices regulations

Clinical benefit	The positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health
Clinical data	The safety and/or performance information that is generated from the use of a device. Clinical data are sourced from: — clinical investigation(s) of the device concerned; or — clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or — published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated
Clinical evaluation	A systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer
Clinical evaluation report	The outcome of the clinical evaluation
Clinical investigation	Any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device
Clinical investigation plan (CIP)	A document that describes the rationale, objectives, design, methodology, monitoring, conduct, record-keeping and method of analysis of a clinical investigation
Clinical investigation report	A report containing documented information on the clinical investigation plan and results and conclusions of the clinical investigation, including negative findings
Clinical performance	The ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user
Clinical performance study plan (CPSP)	A document that describes the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of a clinical performance study
Clinical performance study report (CPSR)	A report containing documented information on the clinical performance study plan and results and conclusions of the clinical performance study, including negative findings
Companion diagnostics (CDx)	A device which is essential for the safe and effective use of a corresponding medicinal product to: • identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or • identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product

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Conformity Assessment	The process a manufacturer must undertake to demonstrate that their device meets the requirements set out in the UK medical devices regulations
Corrective action	Action to eliminate the cause of a potential nonconformity or other undesirable situation. Corrective action is taken to prevent recurrence
Custom-made Medical Device	A relevant device that is— (a) manufactured specifically in accordance with a written prescription of a registered medical practitioner, or other person authorised to write such a prescription by virtue of his professional qualification, which gives, under his responsibility, specific characteristics as to its design; and (b) intended for the sole use of a particular patient, but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user
Declaration of Conformity	A declaration that the device complies with the UK medical devices regulations
Derivative	A 'non-cellular substance' extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case does not contain any cells or tissues
Device deficiency	Any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device / device for performance study, including malfunction, use errors or inadequacy in information supplied by the manufacturer
Device for performance study	A device intended by the manufacturer to be used in a performance study
Directive 90/385/EEC	EU Active Implantable Medical Devices Directive
Directive 90/79/EC	EU *in vitro* Diagnostic Medical Devices Directive
Directive 93/42/EEC	EU General Medical Devices Directive
Distance sales	Medical devices that are sold at a distance via electronic means e.g. via a website or an app store
Distributor	An individual or company involved in the supply chain, other than the importer or manufacturer of the medical device, who supplies or otherwise causes the medical device to be available on the UK market
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 manufacturer's QMS

Economic operator	A manufacturer (including an assembler or steriliser of system of procedure packs), a UK responsible person, an importer or a distributor
EMDN	European Medical Devices Nomenclature
Equivalent device	A medical device that is clinically, technically and biologically the same as another
Essential requirements	The essential requirements set out in Annex 1 of Directive 90/385, Annex I of Directive 93/42 or Annex I of Directive 98/79, as amended by Schedule 2A, which must be met before any device can be placed on the market or put into service and which are intended to ensure that: • a device does not compromise the clinical condition or safety of the patient, the safety and health of users or, where applicable, any third party; • a device achieves its intended purpose as designated by the manufacturer; and • any risks associated with the use of the device are acceptable when weighed against the benefits to the patient and compatible with a high level of protection of health and safety 83.11
Ethics committee	An independent body established in the UK in accordance with the law and empowered to give opinions for the purposes of the UK medical devices regulations - taking into account the views of laypersons, in particular patients or patients' organisations
EU IVDR	EU *in vitro* Diagnostic Medical Devices Regulations (2017/746)
EU MDR	EU Medical Devices Regulations (2017/745)
EUDAMED	EU Database for Medical Devices
Field safety corrective action (FSCA)	An action by a manufacturer to reduce risk of death or serious deterioration in the state of health associated with use of a medical device, i.e. can be a device recall, modification, retrofit or design change, or device destruction
Field safety notice (FSN)	Communication to customers and/or users sent by the manufacturer in relation to an FSCA, explaining the risks involved and what actions the customer needs to take
Fulfilment service provider	A company or organisation that carries out warehousing, packaging addressing and dispatching of medical devices, excluding postal services
Genetic testing	Used to provide information and data on a person’s predisposition to developing a medical condition or disease
GMDN	Global Medical Devices Nomenclature
Health Institution	A body that provides care for patients and promotes public health (e.g. an NHS hospital)
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

IMDRF	International Medica Device Regulators Forum
Implant card / leaflet	A card or leaflet intended to provide patients with information pertaining to either a permanent implantable medical device procedure or an active implantable medical device procedure
Importer	An individual or company located in a given country who places a product on its market from a third country
***In vitro* Diagnostic Medical Device (IVD)**	a medical device which— (a) is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination; and (b) is intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information— (i) concerning a physiological or pathological state, (ii) concerning a congenital abnormality, (iii) to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients, or (iv) to monitor therapeutic measures, and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for *in vitro* diagnostic examination
Incident	Any malfunction or deterioration in characteristics / performance of device or inadequacy in labelling or IFUs which directly or indirectly might lead to death or serious deterioration to health of patient or user
Industrial Scale	Mass-produced by means of industrial manufacturing processes
Informed consent	A subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation / performance study, after having been informed of all aspects of the clinical investigation / performance study that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation / performance study
In-house manufacture	Medical devices that are made in a healthcare establishment to be used for patients within that establishment
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
Intended purpose	(a) in relation to an active implantable medical device, the use for which it is intended and for which it is suited according to the data supplied by the manufacturer in the instructions relating to it;

	(b) in relation to any other medical device, the use to which the device is intended according to the data supplied by the manufacturer on the labelling, the instructions for use and/or the promotional materials
Investigational device	A device that is assessed in a clinical investigation
Investigational site	The site where a clinical investigation / performance study is undertaken that is representative of the intended normal conditions of use of the device in the target patient population
Investigator	An individual responsible for the conduct of a clinical investigation / performance study at a clinical investigation / performance study site, who takes responsibility for the health and safety of the subjects involved
Kit	A set of components that are packaged together and intended to be used to perform a specific *in vitro* diagnostic examination
Label	The written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices
Lay person	An individual who does not have formal education in a relevant field of healthcare or medical discipline
Manufacturer	(a) the person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party; or (b) any other person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name, apart from a person who assembles or adapts devices already on the market to their intended purpose for an individual patient
Market surveillance	The activities carried out and measures taken by public authorities to check and ensure that devices comply with the requirements set out in the relevant legislation and do not endanger health, safety, or any other aspect of public interest protection
Mass-produced	Manufactured in large quantities by an automated mechanical process
Medical Device	Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which— (a) is intended by the manufacturer to be used for human beings for the purpose of- (i) diagnosis, prevention, monitoring, treatment, or alleviation of disease,

	(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, (iii) investigation, replacement, or modification of the anatomy or of a physiological process, or (iv) control of conception; and (b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means, and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device
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) any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or (b) any substance or combination of substances that may be used by or administered to human beings with a view to— (i) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or (ii) making a medical diagnosis. These Regulations do not apply to— (a) whole human blood; or (b) any human blood component, other than plasma prepared by a method involving an industrial process
Medium enterprise	A business with less than 250 employees and an annual turnover under €50 million
MHRA	Medicines and Healthcare products Regulatory Agency
Micro enterprise	A business with less than 10 employees and an annual turnover under €2 million
Nomenclature	A type of coding system used to identify a medical device without the need for terms or descriptions which may not be understood across different languages
Non-viable	Not capable of living or developing successfully
Performance evaluation	An assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device
Performance evaluation report	The outcome of the performance evaluation
Performance study	A study undertaken to establish or confirm the analytical or clinical performance of a device

Periodic safety update report (PSUR)	A post-market surveillance summary from manufacturers of higher risk medical devices including information on the conclusions of the benefit-risk determination, findings of the PMCF/PMPF, the volume of sales of the medical device and information on the use of the medical device
Placing on the market	The first making available in return for payment or free of charge of a new or fully refurbished device, other than a device intended for clinical investigation, with a view to distribution, use, or both, on the UK market
Post-Market Clinical Follow-up (PMCF)	A continuous process of collecting and analysing post-market clinical data from human use of a general medical device over the general medical devices expected lifetime, that updates the clinical evaluation specifically addressed in the manufacturer's post-market surveillance plan
Post-Market Performanc e Follow-up (PMPF)	A continuous process to proactively collect and evaluate performance and relevant scientific data from the use of the IVD over its expected lifetime, that updates the performance evaluation specifically addressed in the manufacturer's post-market surveillance plan
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 for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions
Predetermin ed change control plan	A plan where manufacturers state that their device will change over time, specify a performance metric to track and agree it with a relevant authority. This then means the manufacturer doesn't need to report changes so long as those changes: a) don't change the intended use etc and b) don't deviate from that performance
Principle action	Primary action, main purpose
Proactive market surveillance	Activities which are planned, organised and implemented by the MHRA in its capacity as a Market Surveillance Authority
Procedure pack	A combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose
Putting into service	(a) in relation to an active implantable medical device, the making available of the device to a registered medical practitioner for implantation; (b) in relation to any other medical device, the first making available of the device in UK to a final user, including where a device is used in a professional context for the purposes of medical analysis without being marketed
Qualified person	A person with minimum qualifications or regulatory experience who would be responsible, for example, for ensuring the manufacturer meets the regulatory requirements of the UK medical devices regulations, including

	requirements around the Quality Management System and the post-market surveillance system
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
Reactive market surveillance	Where clear evidence is provided demonstrating a breach in the Regulations has taken place, the MHRA will act on this evidence and undertake market surveillance activities which were not planned in advance
Re-manufacturing	The process whereby a manufacturer cleans, disinfects and sterilises a medical device which is then tested against the re-manufacturer's specifications to ensure the device continues to operate safely and as intended. The company must undergo a conformity assessment by an Approved Body, and obtain a UKCA mark for the re-manufacturing process
Re-processing	Re-processing is similar to re-manufacturing - however the re-processor is not expected to undertake a conformity assessment and place a UKCA mark on the device
Self-declaration	A process whereby a manufacturer can self-declare compliance with the Regulations without going through a third-party conformity assessment
Self-test IVD	An IVD intended by the manufacturer to be able to be used by lay persons in a home environment
Serious adverse incident / event	Any adverse event that led to any of the following: (a) death, (b) serious deterioration in the health of the subject, that resulted in any of the following: (i) life-threatening illness or injury, (ii) permanent impairment of a body structure or a body function, (iii) hospitalisation or prolongation of patient hospitalisation, (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, (v) chronic disease, (c) foetal distress, foetal death or a congenital physical or mental impairment or birth defect
Serious public health threat	An event or incident which could result in an unexpected and widespread public health risk of death, serious illness or serious deterioration in the state of health affecting a significant population, and which may require prompt remedial action
Single-use device	A medical device that is intended to be used on an individual patient during a single procedure
Small enterprise	A business with less than 50 employees and an annual turnover under €10 million
SMEs	Small and medium sized enterprises

Software	A set of instructions that processes input data and creates output data
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))
Sponsor	Any individual, company, institution, or organisation that takes responsibility for the initiation, for the management and setting up of the financing of the clinical investigation / performance study
Subject	An individual who participates in a clinical investigation / performance study
Subsidiary	A company controlled by a “parent” or “holding” company
Sufficient clinical evidence	Clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer
Summary of Safety and Clinical Performance (SSCP)	A mechanism for collating information on the medical device's safety, clinical data, and clinical performance
System	A combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose
Technical documentation	Documentation, data and records that describe the procedures for monitoring and verifying the design of the products
UDI database	The UDI Database is a database which contains identifying information and other elements associated with the specific medical device
UDI device identifier (UDI-DI)	A device identifier specific to a manufacturer and model of medical device
UDI product identifier (UDI-PI)	A product identifier that identifies the unit of medical device production and if applicable the packaged medical devices. The different types of UDI-PIs include serial number, lot number, software identification and, manufacturing date or expiry date or both: **Serial number** uniquely identifiers a single device. **Batch/lot number** identifies a group of devices that have been manufactured together. **Software identification** identifies a batch of a particular version of software. **Manufacturing date** is when the device was made. **Expiry date** is the device's "use-by" date. A device will have at least one of these specified, and in many cases it will have more - which may or may not be included on the label.

UK medical devices regulations	The Medical Devices Regulations 2002 (SI 2002 No 618, as amended)
UK Responsible Person (UKRP)	A person established in any part of the UK who acts on behalf of a manufacturer established outside the UK in relation to specified tasks with regard to the manufacturer's obligations under the UK medical devices regulations
UKCA marking	The UKCA (UK Conformity Assessed) mark is 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. It allows the unambiguous identification of a specific medical device on the market
User	Any healthcare professional or lay person who uses a device
Vigilance	A system of manufacturer awareness and reporting of any incidents involving medical devices that is part of its post-market surveillance activities
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