Appendix

Annex 1 Current UK Medical Devices Regulations Definitions

Term	Application (General Medical Devices / IVDs / Both)	Definition
the 1987 Act	Both	the Consumer Protection Act 1987
accessory	General Medical Devices	an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by its manufacturer
	IVDs	an article intended specifically by its manufacturer to be used together with an *in vitro* diagnostic medical device to enable that device to be used in accordance with its intended purpose, which is not— (a) itself an *in vitro* diagnostic medical device; (b) an invasive sampling medical device; or (c) a medical device which is directly applied to the human body for the purpose of obtaining a specimen
active implantable medical device	General Medical Devices	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
approved body	Both	(1) An approved body is a conformity assessment body which— (a) has been designated by the Secretary of State pursuant to the procedure set out in regulation 45 (designation etc. of approved bodies); or (b) immediately before IP completion day was a UK notified body in respect of which the Secretary of State has taken no action under regulation 45(5) to withdraw a designation.
calibration and control material	IVDs	any substance, material or article intended by its manufacturer either to establish measurement relationships or to verify the performance characteristics of a relevant device in conjunction with the intended use of that device
CE marking	Both	a conformity marking consisting of the initials “CE”
clinical data	Both	the safety or performance information that is generated from the use of a device, derived from— (a) clinical investigations of the device concerned; or (b) clinical investigations or other studies reported in scientific literature of a similar device for which equivalence to the device in question can be demonstrated; or (c) published or unpublished reports on other clinical experiences of either the device in question or a similar device for which equivalence to the device in question can be demonstrated

common technical specification	IVDs	technical specification for a relevant device referred to in a list in Annex II which has been adopted in accordance with the procedure set out in article 7(2) and published in the Official Journal of [the European Union]
custom-made device	General Medical Devices	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
	Active Implantable	an active implantable medical device that is— (a) manufactured specifically in accordance with a medical specialist's written prescription which gives, under his responsibility, specific characteristics as to its design; and (b) intended to be used only for a particular patient
designated standard	Both	a technical specification which is— (a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and (b) designated by the Secretary of State by publishing a reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate
device for performance evaluation	IVDs	product which is intended by its manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analysis or in other appropriate environments outside his own premises
device for self-testing	IVDs	an *in vitro* diagnostic medical device which is intended by its manufacturer to be able to be used by a member of the public in a home environment
Directive 90/385	Active Implantable	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of Member States relating to active implantable devices [as it had effect immediately before IP completion day]
Directive 93/42	General Medical Devices	Council Directive 93/42/EEC of 14 June 1993 concerning medical Devices [as it had effect immediately before IP completion day]
Directive 98/79	IVDs	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices [as it had effect immediately before IP completion day]
Directive 2003/12	General Medical Devices	Commission Directive 2003/12 of 3rd February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC18 concerning medical devices
Directive 2005/50	General Medical Devices	Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices
Directive 2007/47	Both	Directive 2007/47/EC of the European Parliament and of the Council amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market
CAB	Both	the Secretary of State may designate for the purposes of a mutual recognition agreement any corporate or other body as a body which is to carry out any of the tasks of a conformity assessment body, and, if he so designates a body (referred to in these Regulations as an “CAB”), he shall designate the tasks which it is to carry out.
hazard	Both	a potential source of injury or damage to health
hip, knee or shoulder replacement	General Medical Devices	an implantable component part of a total joint replacement system which is intended to provide a function similar to that of either a natural hip joint, a natural knee joint or a natural shoulder joint, other than ancillary components (screws, wedges, plates and instruments)
intended for clinical investigation	General Medical Devices	(a) intended for use by a registered medical practitioner when conducting investigations of that device in an adequate human clinical environment; or (b) intended for use by any other person in [Great Britain] who, by virtue of their professional qualification, is authorised to carry out

		investigations of that device in an adequate human clinical environment
intended purpose	Both	(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
in vitro diagnostic medical device	IVDs	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
machinery	Both	has the meaning given to it by regulation 4 of the Supply of Machinery (Safety) Regulations 2008 https://www.legislation.gov.uk/uksi/2008/1597/regulation/4
manufacturer	Both	(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;
medical device	General Medical Devices	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
the Medical Devices Directives	Both	Directive 90/385, Directive 93/42, [both read with Regulation (EU) No 207/2012 and Regulation (EU) No 722/2012] 34 and Directive 98/79
medicinal product	Both	medicinal product means— (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. (2) 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
mutual recognition agreement	Both	an agreement that— (a) is between the United Kingdom and a country listed in Schedule 2, and (b) covers matters including the conditions under which the United Kingdom and the that country will accept or recognise the results of conformity assessment procedures undertaken by the each other's designated bodies
placing on the market	Both	in relation to a medical device, 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 [and related expressions must be construed accordingly]
putting into service	Both	(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 the UK to a final user, including where a device is used in a professional context for the purposes of medical analysis without being marketed
Regulation (EU) No 207/2012	Both	Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices
Regulation (EU) No 722/2012	Both	Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin
relevant device	Both	The requirements of this Part in respect of relevant devices apply in respect of medical devices (including stable derivatives devices), accessories to such devices, single-use combination products, and systems and procedure packs, other than— (a) active implantable medical devices and accessories to such devices; (b) in vitro diagnostic medical devices and accessories to such devices; and (c) devices that come within the scope of Directive 93/42 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, and (i) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and (ii) the manufacturer chooses to follow the set of arrangements in the other Directive
relevant essential requirements	Both	in relation to a medical device, means 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 which apply to it, but not including, in the case of a device intended for clinical investigation, such of those requirements, or aspects of them, as are the subject of the investigation
single-use combination product	Both	a product which comprises a medical device and medicinal product forming a single integral product which is intended exclusively for use in the given combination and which is not reusable
specimen receptacle	IVDs	medical device which (whether vacuum-type or not) is specifically intended by its manufacturer to be used for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination

stable derivatives device		medical device that contains human blood, blood products, plasma or blood cells of human origin, and which incorporates, as an integral part, a substance which— (a) if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of [regulation 2(2) of the Human Medicines Regulations 2012]; and (b) is liable to act upon the human body with action ancillary to that of the device
supply	General Medical Device	in relation to a medical device, means— (a) the supply of, or the offer or agreement to supply, the device; or (b) the exposure or possession for supply of the device
system or procedure pack	Both	devices bearing the CE marking put together within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the market
third country conformity assessment body	Both	a body established in a country which is listed in Schedule 2 and designated in accordance with a relevant mutual recognition agreement to carry out conformity assessment procedures for the purposes of these Regulations
UK marking	Both	the marking in the form set out in Annex 2
UK responsible person	Both	a person established in any part of the United Kingdom who acts on behalf of a manufacturer established outside the United Kingdom in relation to specified tasks with regard to the manufacturer's obligations under these regulations