STATUTORY INSTRUMENTS

2019 No. 791

The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

PART 2

New Part VIII of the Medical Devices Regulations

10. After regulation 67 of the 2002 Regulations insert—

"PART VIII

Restatement of the Rights, powers, liabilities, obligations, restrictions, remedies and procedures recognised under the Medical Devices Regulation (see regulation 4O)

Scope and Definitions

Subject matter and Scope

68.—(1) This Part lays down the rules for and applies to the placing on the market, the making available on the market and the putting into service of—

(a) medical devices for human use; and

(b) accessories to such medical devices.

(2) This Part also applies to—

(a) clinical investigations concerning medical devices for human use and accessories to such devices; and

(b) the groups of products without an intended medical purpose listed in Schedule 16.

(3) Devices with both an intended medical and non-medical purpose must fulfil the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose.

(4) For the purposes of this Part and Schedules 3 to 16 medical devices, accessories to medical devices and products listed in Schedule 16 are referred to as 'devices'.

(5) The Secretary of State may by Regulations amend the list in Schedule 16.

(6) This Part does not apply to—

(a) relevant devices placed on the market in accordance with Part II or Part III;

(b) subject to paragraph (7), in vitro diagnostic medical devices placed on the market under Part IX;

(c) medicinal products as defined by regulation 2 of the Human Medicines Regulations 2012;

(d) advanced therapy medicinal products covered by regulation 2A of the Human Medicines Regulations 2012;

(e) human blood, human blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market or put into service, such blood products, plasma or cells except for devices referred to in paragraph (8);

(f) cosmetic products covered by Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products;

(g) transplants, tissues or cells of animal origin or their derivatives, or products containing or consisting of them; but this Part does apply to devices which utilise tissues or cells of animal origin (or their derivatives) which are non-viable or rendered non-viable;

(h) transplants, tissues or cells of human origin, or their derivatives, covered by the Human Tissue (Quality and Safety for Human Application) Regulations 2007(**1**) or by the Human Fertilisation and Embryology Act 1990(**2**) or products containing or consisting of them but this Part does apply to devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable;

(i) products, other than those in paragraphs (e), (g) and (h), that contain or consist of viable biological material or viable organisms, including living micro-organisms, bacteria fungi or viruses in order to achieve or support the intended purposes of the product;

(j) food covered by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the principles and requirements of food law, establishing the European Food Safety Agency and laying down procedures in matters of food safety.

(7) Any device which, when placed on the market or put into service, incorporates as an integral part an in vitro diagnostic medical device covered by Part IX, is governed by this Part but the requirements of Part IX also apply to the in vitro diagnostic medical device part of the device.

(8) Subject to sub-paragraph (9), any device which, when placed on the market or put into service, incorporates, as an integral part, a substance which, if used separately, would be considered a medicinal product (including a product derived from human blood or blood plasma) and that has an action ancillary to that of the device, must be assessed and authorised in accordance with this Part.

(9) If the action of the device is ancillary to that of the medicinal product, the product must be governed by the Human Medicines Regulations 2012.

(10) Where paragraph (9) applies, the general safety and performance requirements set out in Schedule 3 must also apply to the device part of the product.

(11) Subject to paragraph (12), any device which is intended to administer a medicinal product is governed by this Part without prejudice to the provisions of the Human Medicines Regulations 2012 .

(12) If the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single integral product must be governed by the Human Medicines Regulations 2012.

(**1**) S.I. 2007/1523.
(**2**) 1990 c. 37.

(13) Where paragraph (12) applies, the relevant general safety and performance requirements set out in Schedule 3 apply to the device part of the single integral product.

(14) A device which, when placed on the market, or put into service, incorporates, as an integral part, non-viable cells of human origin or their derivatives that have an action ancillary to that of the device must be assessed and authorised in accordance with this Part but the provisions for donation, procurement and testing laid down in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 also apply.

(15) If a device which, when placed on the market, or put into service, incorporates, as an integral part, non-viable cells of human origin or their derivatives that have an action which is principal and not ancillary to that of the device and that product is not governed by the Human Medicines Regulations 2012, the product must be governed by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 but the general safety and performance requirements set out in Schedule 3 also apply to the device.

(16) Where a device is also machinery within the meaning of the Supply of Machinery (Safety) Regulations 2008(**3**) and where—

(a) a hazard under that legislation exists; and

(b) the provisions of that legislation are more specific than the general safety and performance requirements set out in Schedule 3,

the device must also meet the essential health and safety requirements set out in Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008.

(17) This Part does not affect the application of the Ionising Radiation (Basic Safety Standards) (Miscellaneous Provisions) Regulations 2018(**4**) or any of the other measures which immediately before exit day transposed Council Directive 2013/59/Euratom(**5**) and which are retained EU law.

(18) This Part does not affect the power of the Secretary of State to restrict the use of any specific type of device in relation to aspects not covered by this Part.

(19) This Part does not affect the organisation, delivery or financing of health services and medical care including—

(a) the rules relating to the supply of medical devices on a medical prescription;

(b) requirements relating to—

(i) the dispensing of medical devices by healthcare institutions or healthcare professionals;

(ii) the use of certain medical devices being accompanied by specific professional counselling.

(20) This Part does not restrict the freedom of the press or freedom of expression in so far as those freedoms are guaranteed under the law.

Definitions

69. In this Part and in Schedules 3 to 16—

"accessory for a medical device" means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical devices to specifically enable the medical device to be used in accordance with its intended purpose or to specifically and directly assist the medical functionality of the medical device in terms of its intended purpose;

(**3**) S.I. 2008/1597.
(**4**) S.I. 2018/482.
(**5**) OJNo. L 13, 17.1.2014, p. 1.

"active device" means—

(a) any device, which depends for its operation on a source of energy (other than that generated by the human body for that purpose, or by gravity) and which acts by changing the density of or converting that energy;

(b) software;

but a device is not an active device if it is intended to transmit energy, substances or other elements between an active device and the patient without any significant change;

"adverse event" means any untoward occurrence, unintended disease or injury or any untoward clinical sign, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device;

"agglomerate", in the definition of "nanomaterial", means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the surface areas of the external components;

"aggregate", in the definition of "nanomaterial", means a particle comprised of strongly bound or fused particles;

"authorised health professional" has the same meaning as in regulation 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004(**6**);

"authorised representative" means any person established outside the United Kingdom but within the European Economic Area who has received and accepted a written mandate from a manufacturer located outside the European Economic Area, to act on the manufacturer's behalf in carrying out certain obligations under Regulation (EU) 2017/745;

"benefit-risk determination" means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;

"CE marking of conformity" or "CE marking" means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Part and with any other applicable legislation;

"clinical benefit" means the positive impact of the device on the health of an individual, expressed in terms of a measurable, meaningful and relevant clinical outcome, including outcomes related to diagnosis, or positive impact on patient management or public health;

"clinical data" means information concerning safety or performance that is generated from the use of a device and is sourced from the following—

(a) clinical investigations of the device concerned;

(b) clinical investigations or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated;

(c) reports published in peer reviewed scientific literature on other clinical experience of either the device or a device for which equivalence to the device in question can be demonstrated;

(d) clinically relevant information coming from post market surveillance, in particular the post-market clinical follow up;

(**6**) S.I. 2004/1031, no relevant amendments.

"clinical evaluation" means a systematic investigation 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 evidence" means 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 benefits, when used as intended by the manufacturer;

"clinical investigation" mean a systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device;

"clinical investigation plan" means a document that describes the rationale, objectives, design, methodology, monitoring, statistical considerations, organisation and conduct of a clinical investigation;

"clinical performance" means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer;

"common specifications" or "CS" must be construed in accordance with regulation 75;

"compatibility" means the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose to do any or all of the following—

(a) perform without losing or compromising the ability to perform as intended,

(b) integrate or operate without the need for modification or adaptation of any part of the combined devices,

(c) be used together without conflict, interference or adverse reaction;

"conformity assessment" means the process demonstrating whether the requirements of this Part have been fulfilled;

"conformity assessment body" means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;

"corrective action" means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation;

"custom-made device" means any device specifically made in accordance with a written prescription of a registered medical practitioner, or any other person authorised to write a prescription by virtue of their professional qualification which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual condition or need but the following devices are not custom-made devices—

(a) mass-produced devices which need to be adapted to meet the specific requirements of a professional user, and

(b) devices which are mass produced by means of an industrial manufacturing process in accordance with the written prescriptions of any authorised person;

"derivative" means a non-cellular substance which has been extracted from human or animal tissue or cells through a manufacturing process but where the final substance used for manufacturing of the device does not itself contain any cells or tissues;

"designated standard" has the same meaning as in regulation 3A;

"device deficiency" in relation to an investigational device means any inadequacy in its identity, quality, durability, reliability, safety or performance, including malfunction, use errors or inadequacy in information supplied by the manufacturer;

"Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use(**7**) as it applies in European Union law;

"distributor" means any person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting it into service;

"economic operator" means a manufacturer, an authorised representative, a UK responsible person, an importer, a distributor or a person referred to in regulation 87(1) and 87(4);

"ethics committee" means an independent body established or recognised under the Care Act 2014(**8**) and empowered to give opinions for the purposes of this Part;

"falsified device" means any device with a false presentation of its identity, of its source or its CE marking certificates or documents relating to CE marking procedures, but a device is not a falsified device where the false presentation is unintentional;

"field safety notice" means a communication sent by the manufacturer to users or customers in relation to field safety corrective action;

"field safety corrective action" means corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of serious incident in relation to a device made available on the market;

"fully refurbishing" (in the definition of "manufacturer") means—

(a) complete rebuilding of a device already placed on the market or put into service; or

(b) the making of a new device from used devices, to bring it into conformity with this Part,

combined with the assignment of a new lifetime to the refurbished device;

"generic device group" means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

"health institution" means an organisation (based in the United Kingdom) the primary purpose of which is the care or treatment of patients or the promotion of public health;

"implantable device" means any device (including those which are wholly or partly absorbed) which is intended through clinical intervention—

(a) to be totally introduced into the human body and to remain in place after the procedure;

(b) to replace an epithelial surface or the surface of the eye and to remain in place after the procedure; or

(c) to be partially introduced into the human body and to remain in place for at least 30 days after the procedure;

"importer" means any person established within the United Kingdom that places on the market a device from a country outside the United Kingdom;

(**7**) OJ No. L 311, 28.11.2001, p. 67 (last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25th October 2012 OJ No. L 299, 27.10.2012, p. 1).
(**8**) 2014 c. 23.

"incident" in relation to a device made available on the market means any malfunction or deterioration in its characteristics or performance of a device, including use-error due to its ergonomic features, any inadequacy in the information supplied by the manufacturer and any undesirable side effects;

"informed consent" means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate or, in the case of minors or incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation;

"instructions for use" means the information provided by the manufacturer to inform the user of the device's intended purpose, proper use and of any precautions to be taken;

"intended purpose" means the use for which the device is intended as set out in—

(a) the data supplied by the manufacturer on the label;

(b) the instructions for use;

(c) the promotional or sales material; or

(d) promotional statements;

and as specified by the manufacturer in the clinical evaluation;

"interoperability" is the ability of two or more devices, including software from the same manufacturer or from different manufacturers, to do any or all of the following—

(a) exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data;

(b) communicate with each other;

(c) work together as intended;

"invasive device" means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body;

"investigational device" means a device that has been assessed in a clinical trial;

"investigator" means the individual responsible for the conduct of a clinical investigation at a clinical investigation site;

"label" means 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" means an individual who does not have formal education in the relevant field of healthcare or medical practice;

"legally designated representative", has the meaning given to the term "legal representative" in Part 1 of Schedule 1(**9**) to the Medicines for Human Use (Clinical Trials) Regulations 2004;

"making available on the market" means any supply of a device, other than an investigational device, for distribution, consumption or use on the United Kingdom market in the course of a commercial activity, whether in return for payment or free of charge and related expressions must be construed accordingly;

(**9**) the definition of "legal representative" in Part I of Schedule 1 to S.I. 2004/1031 was amended by S.I. 2006/1928 r. 27(1)(i)(aa) and (bb).

"manufacturer" means a person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;

"market surveillance" means the activities carried out and measures taken by the Secretary of State to check and ensure that devices comply with the requirements set out in this Part and do not endanger health safety or any other aspect of public interest protection;

"medical device" means—

(a) any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes—

(i) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

(ii) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

(iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

(iv) providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means;

(b) any device for the control or support of conception;

(c) products specifically intended for the cleaning, disinfection or sterilisation of—

(i) medical devices referred to in sub-paragraphs (a) and (b);

(ii) accessories to medical devices; or

(iii) products listed in Schedule 16;

"minor" means a person under the age of 16 years;

"nanomaterial" means—

(a) natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100nm; or

(b) fullerenes, graphene flakes and single wall carbon nanotubes with one of more external dimensions below 1nm;

"non-viable" means having no potential for metabolism or multiplication;

"notified body" means a conformity assessment body designated in accordance with Regulation (EU) 2017/745;

"particle", in the definition of "nanomaterial", means a minute piece of matter with defined physical boundaries;

"performance" means the ability of a device to achieve its intended purpose as stated by the manufacturer;

"placing on the market" means the first making available of a device, other than an investigational device, on the United Kingdom market and related expressions must be construed accordingly;

"post-market surveillance" means 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 purposes of identifying any need to immediately apply any necessary corrective or preventative actions;

"post market clinical follow-up" (PMCF) means a continuous process of updating the clinical evaluation;

"procedure pack" means 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" means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the United Kingdom market for the first time for its intended purpose, and related expressions must be construed accordingly;

"recall" means any measure aimed at achieving the return of a device that has already been made available to the end user;

"Regulation (EU) 2017/745" means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC(**10**) as it has effect in European Union law;

"reprocessing" in relation to a used device means the process, including the cleaning disinfection, sterilisation and related procedures, and the testing and restoration of the technical and functional safety of the device, carried out in order to allow its safe reuse;

"risk" means the combination of the probability of occurrence of harm and the severity of that harm;

"serious adverse event" means 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 body function,

  (iii) hospitalisation or prolongation of hospitalisation,

  (iv) medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or body function,

  (v) chronic disease;

(c) foetal distress, foetal death or congenital physical or mental impairment or birth defect;

"serious incident" means an incident that directly or indirectly led, might have led or might lead to any of the following—

(a) the death of a patient, user or other person;

(**10**) OJ No. L117, 5.5.2017, p. 1.

(b) the temporary or permanent deterioration of a patient's, user's or other person's state of health;

(c) a serious public health threat;

"serious public health threat" means an event which could result in imminent risk of death, serious deterioration in the person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place or time;

"single-use device" means a device that is intended to be used on one individual during a single procedure;

"sponsor" means any person who takes responsibility for the initiation of the clinical investigation, the management of the clinical investigation and the setting up of the financing of the clinical investigation;

"subject" means the individual who participates in the clinical investigation;

"system" means a combination of products, whether or not they are packaged together, which are intended to be interconnected or combined to achieve a specific medical purpose;

"Unique Device Identifier" ('UDI') means a series of numeric or alphanumeric characters that is created through internationally recognised and accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

"UDI system", "UDI database" and related expressions have the meaning given in, or are to be construed in accordance with, in Part C of Schedule 8;

"UK responsible person" has the same meaning as in regulation 2;

"user" means a healthcare professional or lay person who uses a device;

"withdrawal" means any measure aimed at preventing a device in the supply chain from being made available on the market.

Regulatory status of products and amendment of definitions

70.—(1) Subject to paragraph (3), the Secretary of State may by regulations determine whether or not a specific product, or category or group of products, falls within the definition of a medical device or an accessory to a medical device.

(2) The Secretary of State may by regulations amend the definition of "nanomaterial" and associated definitions in regulation 69—

(a) in the light of technical and scientific progress; and

(b) taking into account definitions agreed at international level.

(3) Before making regulations under paragraph (1), the Secretary of State must consult such persons, agencies or bodies as the Secretary of State considers it appropriate to consult.

Making available on the market and putting into service of devices, obligations of economic operators. Reprocessing, CE marking, Free Movement

Placing on the market and putting into service

71.—(1) A device to which this Part applies may be placed on the market or put into service only if it complies with this Part when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

(2) A device to which this Part applies must meet the general safety and performance requirements set out in Schedule 3 which apply to it, taking into account its intended purpose.

(3) Demonstration of the general safety and performance requirements must include a clinical evaluation in accordance with regulation 102.

(4) Devices that are manufactured and used within health institutions must be considered as having been put into service.

(5) With the exception of the relevant safety and performance requirements set out in Schedule 3, the requirements of this Part do not apply to a device which is manufactured and used only within health institutions provided that—

(a) the device is not transferred to another legal entity;

(b) manufacture and use of the device occurs under appropriate quality management systems;

(c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance, by an equivalent device available on the market;

(d) on request from the Secretary of State, the health institution provides the Secretary of State with information (which must include justification for its manufacturing, modification and use of such devices) on the use of the devices;

(e) the health institution draws up and makes publically available a statement setting out—

(i) the name and address of the manufacturing health institution,

(ii) the details necessary to identify the devices,

(iii) a declaration that the devices meet the general safety and performance requirements set out in Schedule 3 or, where applicable, information on which requirements are not fully met and a reasoned justification for not meeting those requirements;

(f) the health institution draws up a document which makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices and the intended purpose, and which is sufficiently detailed to enable the Secretary of State to ascertain whether the general safety and performance requirements set out in Schedule 3 are met;

(g) the health institution takes all necessary measures to ensure that the device is manufactured in accordance with the documentation referred to in sub-paragraph (f);

(h) the health institution reviews experience gained from the clinical use of the devices and takes all necessary corrective actions.

(6) The Secretary of State may require a health institution which has complied with paragraph (5) to provide the Secretary of State with any further information about the devices which it has manufactured or used.

(7) The Secretary of State may restrict the manufacture and the use of a specified type of device manufactured in accordance with paragraph (5) and, for the purpose of considering such a restriction, must be permitted access to inspect the activities of health institutions.

(8) Paragraph (5) does not apply to devices that are manufactured on an industrial scale.

Distance Sales

72.—(1) A device offered by means of information society services to a person established in the United Kingdom must comply with this Part.

(2) A device which is—

(a) not placed on the market;

(b) used for the provision of a diagnostic or therapeutic service used in the context of a commercial activity, whether in return for payment or free of charge; and

(c) offered by means of information society services or by other means of communication (whether directly or through intermediaries) to a person in the United Kingdom,

must comply with this Part.

(3) The Secretary of State may require a person offering a device, as described in paragraph (1) or providing a service described in paragraph (2), to provide the Secretary of State with a copy of the declaration of conformity relating to the device.

(4) In this regulation "information society service" means a "service" within the meaning of Article 1(1)(b) of Directive 2015/1535/EU of the European Parliament and of the Council of 9 September 2015(**11**) (as it has effect in European Union law).

Claims

73. In the labelling, instructions for use, making available, putting into service or advertising of a device a person must not use text, names, trademarks, pictures, figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety or performance by—

(a) ascribing functions and properties to a device which the device does not have;

(b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;

(c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose; or

(d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

Use of designated standards

74.—(1) Devices that are in conformity with the designated standards, or the relevant parts of those standards, are presumed to be in conformity with the requirements of this Part covered by those standards or relevant parts of those standards.

(2) Paragraph (1) also applies to system or process requirements to be fulfilled in accordance with this Part by economic operators or sponsors, including those relating to quality management systems, risk management, post market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow up ('PMCF').

Common Specifications

75.—(1) Subject to paragraphs (5) and (6), in this Part "common specifications" (CS) means common specifications which are—

(**11**) OJ No. L 241, 17.9.2015, p. 1.

(a) adopted by the European Commission in accordance with the procedure set down in Article 9(1) of Regulation (EU) 2017/745; and

(b) designated by the Secretary of State by publishing a reference to the CS and maintaining that publication in a manner in which the Secretary of State considers appropriate.

(2) Devices that comply with CS adopted in accordance with paragraph (1) or specified in regulations made under paragraph (6), are presumed to be in conformity with the requirements of this Part covered by CS or the relevant parts of the CS.

(3) Manufacturers must comply with CS adopted in accordance with paragraph (1), or specified in regulations made under paragraph (6), unless they can justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent to the CS.

(4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw CS to the attention of any person who may have an interest in the CS.

(5) The Secretary of State may cancel the designation of CS by removing from publication the reference to the CS published in accordance with paragraph (1)(b) and, where the Secretary of State has done so, that CS is no longer a CS.

(6) Where the European Commission have not adopted a common specification but the Secretary of State is of the opinion that a common specification is necessary to address urgent public health concerns, the Secretary of State may by regulations specify a CS and publish the CS and designate it in accordance with paragraph (1)(b).

General obligations of manufacturers

76.—(1) When placing devices on the market or putting them into service, manufacturers must ensure that they have been designed and manufactured in accordance with the requirements of this Part.

(2) Manufacturers must establish, document, implement and maintain a system for risk management as described in paragraph 3 of Schedule 3.

(3) Manufacturers must conduct a clinical evaluation in accordance with the requirements set out in regulation 102 and Schedule 14 including PMCF.

(4) Manufacturers of devices other than custom-made devices must draw up and keep up to date technical documentation for those devices.

(5) The technical documentation in paragraph (4) must—

(a) be such as to allow the conformity of the device with the requirements of this Part to be assessed;

(b) include the elements set out in Schedules 4 and 5.

(6) Where the Secretary of State considers it necessary in the light of technical progress, the Secretary of State may by regulations amend Schedules 4 and 5.

(7) Manufacturers of custom-made devices must draw up, keep up to date and keep available for the Secretary of State documentation in accordance with paragraph 12(2) of Schedule 13.

(8) Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, must draw up a declaration of conformity in accordance with regulation 84, and affix the CE marking of conformity in accordance with regulation 85.

(9) Manufacturers must comply with the obligations relating to the UDI system referred to in regulation 91 and with the registration obligations referred to in regulations 93 and 95.

(10) Manufacturers must keep the technical documentation, the declaration of conformity and, if applicable, a copy of any relevant certificate (including amendments and supplements), available for the Secretary of State—

(a) in the case of implantable devices for a period of at least 15 years after the last device covered by the declaration of conformity has been placed on the market;

(b) in the case of all other devices, for a period of at least 10 years after the last device covered by the declaration of conformity has been placed on the market.

(11) The Secretary of State may require a manufacturer to provide the technical documentation and such a request may be for the entirety of the documentation or for a summary.

(12) A manufacturer with a registered place of business outside the United Kingdom must ensure that the person responsible for placing the device on the United Kingdom market has the necessary documentation permanently available.

(13) Manufacturers must ensure that procedures are in place to keep series production in conformity with the requirements of this Part including—

(a) ensuring that changes in device design or characteristics and changes in the designated standards or CS by reference to which the conformity of the device is declared are adequately, and in a timely manner, taken into account;

(b) ensuring that for devices (other than investigational devices) a quality management system, which is proportionate to the risk class and type of device is established, documented, implemented, maintained, kept up to date and continually improved.

(14) The quality management system required by paragraph (13) must—

(a) cover all parts and elements of the manufacturer's organisation dealing with the quality of processes, procedures and devices;

(b) govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Part;

(c) provide details of at least the following—

(i) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

(ii) the identification of applicable general safety and performance requirements and exploration of options to address those requirements;

(iii) the responsibility of the management;

(iv) resource management, including selection and control of suppliers and sub-contractors;

(v) risk management as set out in paragraph 3 of Schedule 3;

(vi) clinical evaluation in accordance with regulation 102 and Schedule 14, including PMCF;

(vii) product realisation, including planning, design, development, production and service provision;

(viii) verification of the UDI assignments made in accordance with regulation 91 to all relevant devices and ensuring consistency and validity of information provided in accordance with regulation 93;

(ix) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with regulation 121;

(x) processes for handling communication with the Secretary of State (and authorities in other relevant states), notified bodies, other economic operators, customers and any other stakeholders;

(xi) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;

(xii) management of corrective and preventive actions and verification of their effectiveness;

(xiii) processes for monitoring and measurement of output, data analysis and product improvement.

(15) Manufacturers must implement and keep up to date the post market surveillance system in accordance with regulation 121.

(16) Manufacturers must ensure that—

(a) the device is accompanied by the information set out in paragraph 23 of Schedule 3;

(b) the particulars on the label are indelible, easily legible and clearly comprehensible to the intended user or patient.

(17) Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Part must—

(a) immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate;

(b) inform the distributors of the device in question and, where applicable, the authorised representative, the UK responsible person and importers accordingly;

(c) where the device presents a serious risk, immediately inform the Secretary of State and, where applicable, the notified body that issued a certificate for the device, in particular, of the non-compliance and of any corrective action taken.

(18) Manufacturers must have a system for recording and reporting incidents and field safety corrective actions as described in regulation 125 and regulation 126.

(19) Manufacturers must, when they are required to do so by the Secretary of State in relation to a device—

(a) provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of the device;

(b) cooperate with the Secretary of State on any corrective action to be taken to eliminate or, if that is not possible, mitigate the risks posed by the device which they have placed on the market or put into service;

(c) provide samples of the device free of charge or, where that is impracticable, grant access to the device.

(20) A manufacturer who fails to cooperate with a requirement made under paragraph (19) may be subject to enforcement action under Part VII or to any other enforcement measures available to the Secretary of State under consumer protection legislation.

(21) Subject to the Data Protection Act 2018(**12**) and to the protection of any intellectual property rights, the Secretary of State must, where there is reason to believe that a device has caused damage and where a request is made in writing by a person in sub-paragraph (a), (b) or (c) facilitate the provision of the information and documentation mentioned in paragraph (19) to—

(a) any person who has been or could have been injured by the device;

(b) any person entitled to bring an action on behalf of the person in sub-paragraph (a); or

(c) any other person reasonably believed to have been affected by the damage caused by the device.

(22) The Secretary of State need not comply with paragraph (21) where disclosure of the information and documentation is to be dealt with in legal proceedings.

(23) Where a manufacturer has entered into an arrangement with another person to design or manufacture a device, the identity of that other person must form part of the information submitted in accordance with regulation 95.

(24) Manufacturers must, taking account of the risk class of a device and the type of device which they produce and the size of their enterprise, hold sufficient insurance (or equivalent financial resources) to meet any potential financial liability arising from damage caused by each such device.

UK responsible person

77. A person regarded as the UK responsible person must—

(a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;

(c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;

(d) forward to the manufacturer any request by the Secretary of State for samples, or access to a device and ensure that the Secretary of State receives the samples or has been given access to the device;

(e) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(f) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

(g) terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the Secretary of State and, if applicable, the relevant notified body of that termination.

(**12**) 2018 c. 12.

General obligations of importers

78.—(1) Importers must only place devices on the market which are in conformity with this Part.

(2) In order to place a device on the market, importers must ensure that—

(a) the device has been CE marked and that the declaration of conformity of the device has been drawn up;

(b) its manufacturer or, if applicable its authorised representative, is identified;

(c) the device is labelled in accordance with this Part and accompanied by the required instructions for use;

(d) where applicable, a UDI has been assigned by the manufacturer in accordance with regulation 91.

(3) Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Part, the importer—

(a) must not place the device on the market until it has been brought into conformity; and

(b) must inform the manufacturer.

(4) Where an importer considers or has reason to believe that a device presents a serious risk or is a falsified device, the importer must also inform the Secretary of State.

(5) Importers must indicate on the device or on its packaging or in a document accompanying the device—

(a) their name,

(b) if applicable, their registered trade name or registered trade mark,

(c) if applicable, their registered place of business or the address at which they can be contacted.

(6) Importers must ensure that any additional label does not obscure information on the label provided by the manufacturer.

(7) Importers must verify that the device has been registered with the Secretary of State and must add their name to the registration.

(8) Importers must—

(a) ensure that while a device is under their responsibility, storage or transport conditions do not jeopardise a device's compliance with the general safety and performance requirements set out in Schedule 3;

(b) comply with any conditions set by the manufacturer.

(9) Importers must keep a register of—

(a) complaints about devices;

(b) non-conforming devices;

(c) recalls of devices;

(d) withdrawals of devices;

and must provide the manufacturer or distributor with any information reasonably requested by them in order to allow them to investigate complaints.

(10) Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Part must—

(a) inform the manufacturer and, if applicable, the authorised representative and the UK responsible person;

(b) cooperate with the manufacturer and the Secretary of State to ensure the necessary corrective action to bring the device into conformity, to withdraw or recall it, is taken.

(11) Where a device presents a serious risk, importers must immediately inform the Secretary of State and, if applicable, the notified body that issued the certificate and must give details of the non-compliance giving rise to the risk and of any corrective action.

(12) Importers who receive complaints from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market must immediately inform the manufacturer and if applicable the authorised representative and the UK responsible person.

(13) Importers must keep the declaration of conformity and any relevant certificate for the period referred to in regulation 76(10).

(14) Importers must, if required by the Secretary of State to do so—

(a) cooperate with the Secretary of State on any action to eliminate or, if that is not possible, mitigate the risks posed, by devices which they have placed on the market;

(b) provide samples of a device or, if that is impractical, grant the Secretary of State access to the device.

General obligations of distributors

79.—(1) When making a device available on the market, distributors must, in the context of their activities, comply with the requirements of this Part.

(2) Before making a device available on the market, distributors must ensure that all the following requirements are met—

(a) the device has been CE marked and the declaration of conformity of the device has been drawn up;

(b) the device is accompanied by the information supplied by the manufacturer in accordance with regulation 76(16);

(c) for imported devices, the importer has complied with the requirements set out in regulation 78(5);

(d) that, where applicable, a UDI has been assigned by the manufacturer.

(3) In order to meet the requirements of sub-paragraphs (a), (b) and (d) of paragraph (2) the distributor may apply a sampling method that is representative of the devices supplied by the distributor.

(4) Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Part, the distributor must—

(a) not make the device available on the market until it has been brought into conformity;

(b) inform the manufacturer;

(c) where applicable, inform the importer, the authorised representative and the UK responsible person.

(5) Where a distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, the distributor must, in addition to complying with paragraph (4) also inform the Secretary of State.

(6) Distributors must ensure that, while the device is under their responsibility, storage and transport conditions comply with the conditions set by the manufacturer.

(7) Where a distributor considers or has reason to believe that a device which that distributor has made available on the market is not in conformity with this Part, the distributor must—

(a) inform the manufacturer and where applicable, the manufacturer's authorised representative, the UK responsible person and the importer;

(b) cooperate with the manufacturer and with the Secretary of State and, where applicable, the manufacturer's authorised representative, UK responsible person and the importer to ensure the necessary corrective action to bring the device into conformity, to withdraw or to recall the device, is taken.

(8) Where the distributor considers or has reason to believe that a device which it has made available on the market presents a serious risk it must immediately inform the Secretary of State.

(9) Distributors must, unless the relevant information will be provided by another economic operator, upon request by the Secretary of State, provide the Secretary of State with all the information at their disposal and necessary to demonstrate the conformity of the device.

(10) Distributors must, at the Secretary of State's request—

(a) cooperate with the Secretary of State on any action taken to eliminate the risks posed by devices which they have made available on the market;

(b) provide free samples of the device or, if that is impractical, grant the Secretary of State access to the device.

Person responsible for regulatory compliance

80.—(1) Subject to paragraph (4), manufacturers must have available within their organisation at least one person who is responsible for regulatory compliance and who possesses the requisite expertise in the field of medical devices.

(2) Subject to paragraph (3), the requisite expertise in paragraph (1) may be demonstrated by either of the following—

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised by the Secretary of State as equivalent in—

(i) law,

(ii) medicine,

(iii) pharmacy,

(iv) engineering, or

(v) another relevant scientific discipline,

and at least one year of professional experience in regulatory affairs management relating to medical devices;

(b) 4 years of professional experience in—

(i) regulatory affairs, or

(ii) in quality management systems relating to medical devices.

(3) Where a manufacturer manufactures custom-made devices the requisite experience may be demonstrated by having at least 2 years of professional expertise within a relevant field of manufacturing.

(4) Micro and small businesses, within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises(**13**) (as it has effect in European Union law), are not required to have a person responsible for regulatory compliance within their organisation but must have such a person permanently and continuously at their disposal.

(5) The person responsible for regulatory compliance must at least be responsible for ensuring that—

(a) the conformity of devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before the device is released;

(b) the technical documentation and declaration of conformity are drawn up and kept up-to date;

(c) the post market surveillance obligations are complied with in accordance with regulation 76(15);

(d) the reporting obligations referred to in regulations 125 to 128 are fulfilled;

(e) in the case of investigational devices, the statement referred to in paragraph 4(1) of Chapter II of Schedule 15 is issued.

(6) If a number of persons are jointly responsible for regulatory compliance their respective areas of responsibility must be stipulated in writing.

(7) The person responsible for regulatory compliance must not suffer any disadvantage within the manufacturer's organisation in relation to the person's proper fulfilment of their duties, regardless of whether or not they are employees of the organisation.

Cases in which obligations of manufacturers apply to importers, distributors or other persons

81.—(1) A distributor, importer or other person has the obligations of a manufacturer if that person does any of the following—

(a) makes available on the market a device under its name, registered trade name or registered mark, except in cases where a distributor or importer enters into an agreement with manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Part;

(b) changes the intended purpose of a device already placed on the market or put into service;

(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

(2) Paragraph (1) does not apply to a person who, without changing its intended purpose, assembles or adapts for an individual patient a device which is already on the market.

(3) For the purposes of paragraph (1)(c) the following are not to be considered to be a modification of a device that could affect its compliance with the applicable requirements—

(a) provision of information supplied by the manufacturer, in accordance with paragraph 23 of Schedule 3, relating to a device already on the market and of further information which is necessary in order to market the device;

(b) changes to the outer packaging of a device already placed on the market, including a change of the pack size, if the repackaging is carried out in such conditions

(**13**) OJ No. L 124, 20.5.2003, p. 36.

that the original condition of the device cannot be affected but, for devices placed on the market in a sterile condition, the original condition of the device must be presumed to be adversely affected if the packaging necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

(4) A distributor or importer that carries out any of the activities mentioned in paragraph (3) must indicate on the device or, where that is impractical, on the packaging or in a document accompanying the device—

(a) the activity carried out;

(b) the name of the importer or distributor;

(c) any registered trade name or trade mark of the importer or distributor;

(d) the registered place of business and the address at which the importer or distributor can be contacted.

(5) Distributors and importers who carry out the activities in paragraph (3) must have a quality management system in place which—

(a) ensures that the activities in paragraph (3) are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy;

(b) contains procedures which ensure that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in order to respond to safety issues or to bring the device into conformity with this Part.

(6) At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities in paragraph (3) must—

(a) inform the manufacturer and the Secretary of State of the intention to make a relabelled or repackaged device available;

(b) upon request, provide the manufacturer and the Secretary of State with a sample or mock-up of the relabelled or repackaged device (including any translated label and instructions for use);

(c) submit to the Secretary of State a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in paragraph (3), attesting that the quality management system of the distributor or importer complies with the requirements laid down in paragraph (4).

Single-use devices and their reprocessing

82.—(1) Reprocessing and further use of single-use devices may only take place in accordance with this Part.

(2) Subject to paragraph (4), any person who reprocesses a single-use device to make it suitable for further use must be considered a manufacturer of the reprocessed device and must assume the obligations of a manufacturer in this Part.

(3) A person who reprocesses a device must be considered to be the producer for the purposes of Part I of the 1987 Act.

(4) Where single-use devices are reprocessed and used within a health institution, the Secretary of State may direct that not all the rules relating to manufacturers obligations laid down in this Part apply provided that the following conditions are met—

(a) the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements of regulation 71(5) are complied with;

(b) the reprocessing is performed in accordance with the CS detailing requirements concerning—

(i) risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing;

(ii) the validation of procedures for the entire process, including cleaning steps;

(iii) the product release and performance testing;

(iv) the quality management system;

(v) the reporting of incidents involving devices that have been reprocessed; and

(vi) the traceability of reprocessed devices.

(5) The Secretary of State must encourage and may require health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other information on the reprocessed devices that patients are treated with.

(6) The Secretary of State may also direct that the provisions of paragraph (4) apply where single-use devices are processed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to the health institution and the external reprocessor complies with the requirements of paragraph (4).

(7) Reprocessing of devices may only be performed in accordance with any designated standards that cover the matters outlined in paragraph (4)(b) and may not be performed unless such designated standards have been adopted.

(8) Only single-use devices that have been placed on the market in accordance with Part II or this Part of these Regulations may be reprocessed.

(9) Only reprocessing of single-use devices that are considered safe according to the latest scientific evidence may be carried out.

(10) The name and address of the person referred to in paragraph (2) and the other relevant information referred to in paragraph 23 of Schedule 3 must be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

(11) The name and address of the manufacturer of the original single-use device must no longer appear on the label, but must be mentioned in the instructions for use of the reprocessed device.

Implant card and information to be supplied to the patient with an implanted device

83.—(1) The manufacturer of an implantable device must provide, together with the device, the following—

(a) information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

(b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;

(c) any information about the expected lifetime of the device and any necessary follow-up;

(d) any other information to ensure safe use of the device by the patient, including the information in paragraph (u) of sub-paragraph (6) of paragraph 23 of Schedule 3.

(2) The information referred to in paragraph (1)—

(a) must be provided, for the purpose of making it available to the particular patient who has been implanted with the device, by means that allow rapid access to the information;

(b) must be written in a way that is readily understood by a lay person and must be updated where appropriate, such updates being made available to the patient on the manufacturer's website;

(c) for the information referred to in paragraph (1)(a), must be on an implant card delivered with the device.

(3) Health institutions must—

(a) make the information referred to in paragraph (1) available by means which allow rapid access to that information, to any patients who have been implanted with the device,

(b) provide those patients with the implant card.

(4) The requirements of this regulation do not apply to the following implants—

(a) Sutures;

(b) Staples;

(c) dental fillings;

(d) dental braces;

(e) tooth crowns;

(f) screws;

(g) wedges;

(h) plates;

(i) wires;

(j) pins;

(k) clips;

(l) connectors.

(5) The Secretary of State may, by regulations, amend the list in paragraph (4) by adding other types of implants to it or by removing implants from the list.

Declaration of conformity

84.—(1) The declaration of conformity must state that the requirements specified in this Part or, where relevant, in Regulation (EU) 2017/745 or both sets of requirements, have been fulfilled in relation to the device that is covered.

(2) The manufacturer must continuously update the declaration of conformity and the declaration of conformity must—

(a) contain the information set out in Schedule 6;

(b) be in English.

(3) Where a device is subject to other legislation which requires a declaration of conformity by the manufacturer, a single declaration of conformity must be drawn up in respect of all the legislation applicable to the device and must contain the information required for identification of the legislation to which the declaration relates.

(4) By drawing up the declaration of conformity, the manufacturer assumes responsibility for compliance with the requirements of this Part and all other legislation applicable to the device.

CE marking of conformity

85.—(1) Devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of this Part must bear the CE marking of conformity set out in Schedule 7.

(2) The CE marking—

(a) must be affixed visibly, legibly and indelibly to the device or its sterile packaging;

(b) where such affixing is not possible or not warranted on account of the nature of the device, must be affixed to the packaging;

(c) must also appear in any instructions for use and on any sales packaging.

(3) The CE marking must be affixed before the device is placed on the market and may be followed by a pictogram or any other mark indicating a special risk or use.

(4) Where applicable, the CE marking must be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in regulation 98 and the identification number must also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

(5) Where devices are subject to other legislation which also provides for the affixing of the CE marking, the CE marking must indicate that the devices also fulfil the requirements of that other legislation.

Devices for special purposes

86.—(1) The Secretary of State must not create obstacles to—

(a) investigational devices being supplied to an investigator for the purpose of a clinical investigation if they meet the requirements of this Part;

(b) custom made devices which meet the requirements of this Part.

(2) Other than investigational devices which already bear a CE marking, the devices to which paragraph (1) relates must not bear a CE marking.

(3) Custom-made devices must be accompanied by the statement referred to in paragraph 1 of Schedule 13 which must be identified by name, an acronym or a numerical code.

(4) The Secretary of State may require a manufacturer of a custom-made device to send to the Secretary of State a list of such devices.

(5) The Secretary of State must not create obstacles to the showing of devices, which do not comply with this Part, at trade fairs, exhibitions, demonstrations or similar events provided that the following conditions are met—

(a) a visible sign clearly indicates that such a device is intended for presentation or demonstration purposes;

(b) that such a device cannot be made available until it has been brought into compliance with this Part.

System and procedure packs

87.—(1) A person who combines devices bearing a CE mark with other devices or products listed in paragraph (2), in a manner that is compatible with the intended purpose

of the devices or other products and within the limits specified by their manufacturer, for the purpose of placing them on the market as a system or procedure pack, must draw up a statement.

(2) The devices or other products mentioned in paragraph (1) are—

(a) other devices bearing the CE marking;

(b) in vitro diagnostic medical devices bearing the CE marking in conformity with Part IX;

(c) other products which conform with legislation that applies to them only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified.

(3) In the statement required by paragraph (1), the person must declare that—

(a) they have verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturer's instructions and have carried out their activities in accordance with those instructions;

(b) they packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;

(c) the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

(4) Any person who sterilises system or procedure packs referred to in paragraph (1) for the purpose of placing them on the market, may apply either the procedure set out in Schedule 10 or the procedure set out in Part A of Schedule 12 and must draw up a statement declaring that the sterilisation has been carried out in accordance with the manufacturer's instructions.

(5) Where —

(a) a system or procedure pack consists of devices or products which do not bear the CE marking;

(b) the chosen combination of devices is not compatible (having regard to their original intended purpose); or

(c) sterilisation has not been carried out in accordance with the manufacturer's instructions the system or procedure pack must be treated as a device in its own right, must be subject to the relevant conformity assessment procedure in regulation 98 and the person who creates the system or procedure pack must assume the obligations of a manufacturer.

(6) The system or procedure packs referred to in paragraph (1)—

(a) must not themselves bear an additional CE marking;

(b) must bear the name, registered trade name or registered trade mark and the address of the person intending to place a system or procedure pack on the market in accordance with paragraphs (1) or (3);

(c) must be accompanied by the information referred to in paragraph 23 of Schedule 3.

(7) The statement referred to in paragraph (2) must be kept, in respect of the devices which have been combined, at the disposal of the Secretary of State for the period specified in regulation 76(10) and, where different periods would apply to different devices within the system or procedure pack, the longest period must apply.

Parts and components

88.—(1) Any person who makes available on the market an item specifically intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose, must—

(a) ensure that the item does not adversely affect the safety and performance of the device; and

(b) keep available supporting evidence of that for the Secretary of State.

(2) An item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device is considered to be a device and must meet the requirements laid down in this Part.

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance and clinical performance

Identification within the supply chain

89.—(1) Distributors and importers must cooperate with manufacturers (or, if applicable, the manufacturer's authorised representative and UK responsible person) to achieve an appropriate level of traceability of devices.

(2) Economic operators must, where applicable, be able to identify the following to the Secretary of State, for the period referred to in regulation 76(10)—

(a) any economic operator to whom they have directly supplied a device;

(b) any economic operator who has directly supplied them with a device;

(c) any health institution or healthcare professional to which they have directly supplied a device.

Medical devices nomenclature

90.—(1) The Secretary of State must ensure that an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other persons required by this Part to use that nomenclature.

(2) The Secretary of State must also endeavour to ensure that nomenclature is available to other stakeholders free of charge, where reasonably practicable.

Unique device identification system

91.—(1) 'UDI system' must consist of –

(a) production of a UDI that comprises—

(i) a UDI device identifier ('UDI-DI') specific to a manufacturer and a device, providing access to the information laid down in Part B of Schedule 8;

(ii) a UDI production identifier ('UDI-PI') that identifies the unit of device production and if applicable the packaged devices, as specified in Part C of Schedule 8;

(b) placing of the UDI on the label of the device or on its packaging;

(c) storage of the UDI by economic operators, health institutions and healthcare professionals, in accordance with the conditions laid down in paragraphs (8) and (9) of this regulation respectively;

(d) establishment of an electronic system for Unique Device Identification ('UDI database') in accordance with regulation 94.

(2) Before placing a device, other than a custom-made device, on the market, the manufacturer must assign to the device and, if applicable, to all higher levels of packaging, a UDI created in compliance with the rules of an issuing entity.

(3) Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer must ensure that the information referred to in Part B of Schedule 8 about the device is correctly submitted and transferred to the UDI database referred to in regulation 94.

(4) UDI carriers must be placed on the label of the device and on all higher levels of packaging but "higher levels of packaging" does not include shipping containers.

(5) The UDI must be used for reporting serious incidents and field safety corrective actions in accordance with regulation 125.

(6) The Basic UDI-DI of the device must appear on the declaration of conformity referred to in regulation 84.

(7) As part of the technical documentation referred to in Schedule 4 the manufacturer must keep up-to-date a list of the UDIs that it has assigned.

(8) Economic operators must store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to—

(a) Class III implantable devices;

(b) the devices, categories or groups of devices determined by regulations made under paragraph (12)(a).

(9) Health institutions must store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices are Class III implantable devices.

(10) For devices other than Class III implantable devices, the Secretary of State may require, health institutions to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied.

(11) The Secretary of State may require healthcare professionals to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied.

(12) The Secretary of State may by regulations—

(a) determine the devices, categories or groups of devices mentioned in paragraph (8);

(b) amend the list of information set out in Part B of Schedule 8 in the light of technical progress;

(c) amend Schedule 8 in the light of international developments and technical progress.

(13) In this regulation, regulation 93 and Schedule 8 "issuing entity" means an organisation designated by the European Commission for the purpose of issuing UDIs pursuant to Regulation (EU) 2017/745.

UDI database

92.—(1) The Secretary of State must set up and manage a UDI database to validate, collate, process and make available to the public the information mentioned in Part B of Schedule 8.

(2) The UDI database may be a separate database or form part of a larger database which may include the system required by regulation 94.

(3) In designing the UDI database, the Secretary of State must—

(a) take into account the general principles set out in paragraph 5 of Part C Schedule 8;

(b) ensure that UDI-PIs and commercially confidential product information cannot be included in the database.

(4) The core data elements to be provided to the UDI database, referred to in Part B of Schedule 8 must be accessible to the public free of change.

(5) The technical design of the UDI database must ensure maximum accessibility to information, including multi-user access and automatic uploads and downloads of that information.

(6) The Secretary of State must provide for technical and administrative support to manufacturers and other users of the UDI database.

(7) The UDI database must also be set up to manage the information and core data elements in respect of devices falling under Part IX.

Registration of devices

93.—(1) Before placing a device, other than a custom-made device, on the market, the manufacturer must, in accordance with the rules of the issuing entity referred to in regulation 91(13), assign a Basic UDI-DI, as defined in Part C of Schedule 8, to the device and must provide it to the Secretary of State together with the other core data elements referred to in—

(a) Part B of Schedule 8 related to that device;

(b) Paragraph 2 in Part A of Schedule 8.

(2) Before placing on the market a system or procedure pack pursuant to regulation 87(1) and (4), that is not a custom-made device, the person responsible must assign to the system or procedure pack, in compliance with the rules of the issuing entity, a Basic UDI-DI and must provide it to the UDI database together with the other core data elements referred to in Part B of Schedule 8 related to that system or procedure pack.

(3) Where a manufacturer is not established in the United Kingdom, the UK responsible person must ensure that the manufacturer has complied with paragraphs (1) or (2).

Electronic system for registration of devices and economic operators

94. The Secretary of State must set up and manage an electronic system to—

(a) create a registration number for the purpose of identifying the manufacturer and, where applicable, the importer, authorised representative, the UK responsible person and distributor; and

(b) register the information provided for in paragraph 1 and paragraph 2 (with the exception of paragraph 2(b)) of Part A of Schedule 8.

Registration of economic operators

95.—(1) No person may place a device, other than a custom made device, on the market, unless that person is—

(a) established in the United Kingdom;

(b) has complied with paragraph (2).

(2) Before placing a device, other than a custom made device, on the market—

(a) a manufacturer, falling within paragraph (1)(a), must register with the electronic system referred to in regulation 94 and provide the information set out in paragraph 1 of Part A of Schedule 8;

(b) where there is no manufacturer established in the United Kingdom, the person placing the product on the market is to be regarded as the UK responsible person and that person must register with the electronic system referred to in regulation 94 and provide the information set out in paragraph 1 of Part A of Schedule 8.

(3) Unless they have already registered as a person within paragraph (2)(b), importers must also provide the relevant information in paragraph 1 of Part A of Schedule 8.

(4) Within one week of a change occurring in the information referred to in paragraph (2), the person providing the relevant information in accordance with paragraphs (2) or (3) must update the information in the electronic system referred to in regulation 94.

(5) Not later than one year after the submission of the information referred to in paragraph (2), and every second year after that, the person must confirm the accuracy of the information.

(6) Notwithstanding the person's responsibility for the accuracy of the information, the Secretary of State must verify the information provided under paragraph (2).

(7) The information entered in the electronic system must be accessible to the public.

(8) The Secretary of State may use the information provided under paragraph (2) for the purpose of charging a fee in connection with carrying out the activities set out in this Part.

Summary of safety and clinical performance

96.—(1) For implantable devices and for Class III devices, other than custom-made or investigational devices, a manufacturer must draw up a summary of safety and clinical performance.

(2) The summary of safety and clinical performance must be written in a way that is clear to the intended user and, if applicable, to the patient and must be made available to the public.

(3) The manufacturer must state on the label or the instructions for use where the summary of safety and clinical performance can be found.

(4) The summary of safety and clinical performance must include at least the following—

(a) identification of the device and the manufacturer including the Basic UDI-DI;

(b) the intended purpose of the device, any indications or contraindications and the target populations;

(c) a description of the device, including a reference to any previous generations or variants and a description of the differences;

(d) where relevant, a description of any accessories, other devices and products which are intended to be used in combination with the device;

(e) possible diagnostic therapeutic alternatives;

(f) the summary of clinical evaluation as referred to in Schedule 14, and relevant information on post-market clinical follow-up;

(g) suggested profile and training for users;

(h) information on any residual risks and any undesirable side effects, warnings and precautions.

(5) The Secretary of State may by regulations set out the form and presentation of the data elements to be included in the summary of safety and clinical performance.

Classification and conformity assessment

Classification of devices

97. Devices must be divided into Classes I, IIa, IIb and III according to the classification rules in Schedule 9.

Conformity assessment procedures

98.—(1) Subject to regulation 100, before placing a device on the market, putting a device into service or making a device available on the market, a person must ensure that the manufacturer has undertaken an assessment of the conformity of the device in accordance with the applicable conformity assessment procedures outlined in paragraphs (2) to (10) and set out in Schedules 10 to 12.

(2) Class III devices, other than custom-made or investigational devices, must be subject to—

(a) a conformity assessment as specified in Chapters I and III of Schedule 10; or

(b) a conformity assessment as specified in Schedule 11 coupled with a conformity assessment as specified in Schedule 12.

(3) Subject to paragraph (4), Class IIb devices, other than customer-made or investigational devices, must be subject to a conformity assessment—

(a) as specified in Chapters I and III of Schedule 10, including an assessment of the technical documentation as specified in paragraph 2 of that Schedule of at least one representative device per generic device group; or

(b) a conformity assessment based on type examination as specified in Schedule 11 coupled with a conformity assessment based on product conformity verification as specified in Schedule 12.

(4) For Class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the assessment of the technical documentation as specified in paragraph 2 of Schedule 10 must apply for every device.

(5) The Secretary of State may, by regulations, add to, or remove items from, the list of exempted Class IIb devices in paragraph (4), but the Secretary of State may only add to that list where the technology is well established and where the technology is similar to the devices listed.

(6) Class IIa devices, other than custom made or investigational devices, must be subject to—

(a) a conformity assessment as specified in Chapters I and III of Schedule 10, including an assessment of the technical documentation as specified in paragraph

2 of that Schedule of at least one representative device for each category of devices; or

(b) a conformity assessment specified in paragraph 8 or paragraph 12 of Schedule 12 along with the technical documentation (as set out in Schedules 4 and 5 for at least one representative device for each category of device.

(7) Subject to paragraph (8), Class I devices, other than custom-made or investigational devices, must be subject to a conformity assessment procedure which consists of the manufacturer issuing the declaration of conformity referred to in regulation 84 after drawing up the technical documentation set out in Schedules 4 and 5.

(8) If Class I devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer must apply the procedures set out in—

(a) Chapters I and III of Schedule 10; or

(b) Part A of Schedule 12.

(9) Subject to paragraph (10), custom-made devices must be subject to the conformity assessment procedure set out in Schedule 13 and draw up the statement set out in paragraph 1(g) of that Schedule.

(10) Class III custom made implantable devices must, in addition to the procedure in paragraph (9), be subject to—

(a) the conformity assessment specified in Chapter I of Schedule 10; or

(b) the conformity assessment specified in Part A of Schedule 12.

(11) Devices which incorporate a medicinal product the action of which is ancillary to that of the device as set out in regulation 68(8), must, in addition to the procedures set out in paragraphs (2), (3), (6) or (7), also be subject to the procedure specified in Section 5.2 of Annex IX or, if applicable, Section 6 of Annex X to Regulation (EU) 2017/45.

(12) Devices which are manufactured utilising animal or human tissues and which fall within this Part in accordance with regulation 68(6)(g) and 68(6)(h), must, in addition to the procedures set out in paragraphs (2), (3), (6) or (7), also be subject to the procedure specified in Section 5.3 of Annex IX or that Section read with Section 6 of Annex X to Regulation (EU) 2017/745.

(13) Investigational devices must be subject to the requirements set out in regulations 103 to 119.

Involvement of notified bodies in conformity assessment procedures

99.—(1) Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of its choice, provided that the chosen notified body is designated for conformity assessment activities related to the types of devices concerned.

(2) The manufacturer may not lodge an application in parallel with another notified body for the same conformity assessment procedure.

Exceptions to the conformity assessment procedures

100.—(1) The requirements of regulation 98 do not apply where, on request, the Secretary of State has authorised the placing on the market, making available on the market or putting into service within the United Kingdom of a specific device and where that authorisation is granted for the purpose of protecting public health or patient safety or health.

(2) Except for the requirement to register in accordance with regulations 93 or 95, the requirements of this Part do not apply where the Secretary of State directs that a relevant device (or a class of relevant devices), which meets other requirements or standards (or which is marked other than with a CE marking) which the Secretary of State considers to be equivalent to the requirements and standards imposed by this Part, may be placed on the market.

(3) In paragraph (2), a standard or requirement is equivalent to a standard or requirement imposed by this Part if, in respect of the relevant device (or class of relevant devices), the standard or requirement provides for an equivalent level of safety and quality to that imposed by this Part.

Certificate of free sale

101.—(1) For the purpose of export and upon request by a manufacturer, the Secretary of State must issue a certificate of free sale declaring that the manufacturer has its registered place of business in the United Kingdom and that the device in question, bearing the CE marking in accordance with this Part, may be marketed in the United Kingdom.

(2) The certificate of free sale must set out the Basic UDI-DI of the device as provided to the UDI database under regulation 92 and, where a notified body has issued a certificate, the certificate of free sale must set out the unique number identifying the certificate issued by the notified body.

Clinical evaluation and clinical investigations

Clinical evaluation

102.—(1) Conformity with the relevant general safety and performance requirements set out in Schedule 3, the evaluation of undesirable side-effects and the acceptability of the benefit-risk-ratio referred to in paragraphs 1 and 8 of Schedule 3, must be based on clinical data which provides sufficient clinical evidence and, where applicable, the relevant data referred to in Schedule 5.

(2) The manufacturer must specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements and that level of clinical evidence must be appropriate in view of the characteristics of the device and its intended purpose.

(3) Manufacturers must plan, conduct and document a clinical evaluation in accordance with this Part and with Part A of Schedule 14.

(4) A clinical evaluation must be based on the following—

(a) a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where the following conditions are satisfied—

(i) it is demonstrated that the device subject to clinical evaluation for the intended purpose is equivalent to the device to which the data relate, in accordance with paragraph 3 of Schedule 14,

(ii) the data adequately demonstrate compliance with the relevant general safety and performance requirements;

(b) a critical evaluation of the results of all available clinical investigations, taking duly into consideration whether the investigations were performed under regulations 103 to 119 and Schedule 15;

(c) a consideration of currently available alternative treatment options for that purpose, if any.

(5) Subject to paragraphs (6), (8) and (9), clinical investigations must be performed for implantable devices and Class III devices.

(6) A clinical investigation need not be performed on an implantable device or a Class III device if the following conditions are met—

(a) the device has been designed by modifying a device already marketed by the same manufacturer;

(b) the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device, in accordance with paragraph 3 of Schedule 14 and this demonstration has been endorsed by the notified body;

(c) the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.

(7) For the purposes of paragraph (6)(c), the Secretary of State may request the PMCF plan for the purposes of checking that the plan is appropriate and includes post market studies to demonstrate the safety and performance of the device.

(8) A clinical investigation need not be performed on an implantable device or a Class III device if, in addition to the conditions set out in paragraph (6), the following conditions are also met—

(a) the device (the second device) has been demonstrated by its manufacturer to be equivalent to a device (the first device) which has already been marketed by a manufacturer other than manufacturer of the second device;

(b) the two manufacturers have a contract in place which explicitly allows the manufacturer of the second device full access, on an ongoing basis, to the technical documentation of the relating to the first device;

(c) the clinical evaluation of the first device was performed in compliance with this Part or Regulation (EU) 2017/745 and the manufacturer of the second device provides clear evidence of that to the Secretary of State.

(9) A clinical investigation need not be performed on any of the following list of implantable devices or Class III devices provided the clinical evaluation is based on sufficient clinical data and the device is in compliance with a designated standard—

(a) devices which have been lawfully placed on the market or put into service in accordance with Parts II or III of these Regulations and for which the clinical evaluation—

(i) is based on sufficient clinical data, and

(ii) is in compliance with the relevant product-specific CS for clinical evaluation of that kind of device, where such CS is available; or

(b) devices that are—

(i) staples,

(ii) sutures,

(iii) dental fillings,

(iv) dental braces,

(v) tooth crowns,

(vi) screws,

(vii) wedges,

(viii) plates,

(ix) wires,

(x) pins,

(xi) clips, or

(xii) connectors.

(10) Where justified in view of well-established technologies, similar to those used in the devices listed in paragraph (9)(b), and where justified in order to protect the health and safety of individuals or to protect public health generally, the Secretary of State may by regulations amend the list in paragraph (9)(b) by adding or removing devices from the list.

(11) In the case of products without an intended medical purpose listed in Schedule 16—

(a) the requirement to demonstrate a clinical benefit in accordance with this Part must be understood as a requirement to demonstrate the performance of the device;

(b) clinical evaluations of these products must be based on relevant data concerning safety (including data from post-market surveillance, PMCF and where applicable specific clinical evaluation);

(c) clinical investigations must be performed for these products unless reliance on existing clinical data from an analogous medical device is duly justified.

(12) Without prejudice to paragraph (5), where the demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception—

(a) must be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer;

(b) the manufacturer must duly substantiate in the technical documentation referred to in Schedule 4 why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, to be adequate.

(13) The clinical evaluation and its documentation must be updated throughout the life cycle of the device concerned with—

(a) clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Schedule 14 and the post-market surveillance plan referred to in regulation 122;

(b) for Class III devices and implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance referred to in regulation 96 must be updated at least annually.

(14) The clinical evaluation, its results and the clinical evidence derived from it must be documented in a clinical evaluation report as referred to in paragraph 4 of Schedule 14, which, except for custom-made devices, must be part of the technical documentation referred to in Schedule 4 relating to the device concerned.

General requirements regarding clinical investigations conducted to demonstrate conformity of devices

103.—(1) Where they are carried out as part of a clinical evaluation for the purposes of a conformity assessment with a view to placing a device on the market, clinical investigations

must be designed, authorised, conducted, recorded and reported in accordance with the provisions of this regulation and in particular regulations 104 to 119 and Schedule 15, and carried out for one or more of the following purposes—

(a) to establish and verify that, under normal conditions of use, a device is designed, manufactured and packaged in such a way that falls within the definition of a medical device in regulation 69, and achieves the performance intended as specified by its manufacturer;

(b) to establish and verify the clinical benefits of a device as specified by its manufacturer;

(c) to establish and verify the clinical safety of the device and to determine any undesirable side-effects, under normal conditions of use of the device, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device.

(2) Where the sponsor of a clinical investigation is not established in the United Kingdom—

(a) that sponsor must ensure that a person is established in the United Kingdom as its legal representative;

(b) such legal representative must be responsible for ensuring compliance with the sponsor's obligations pursuant to this Part, and must be the addressee for all communications with the sponsor provided for in this Part;

(c) any communication with that legal representative must be deemed to be a communication with the sponsor.

(3) Clinical investigations must be designed and conducted in such a way that—

(a) the rights, safety, dignity and well-being of the subjects participating in a clinical investigation are protected and prevail over all other interests;

(b) the clinical data generated are scientifically valid, reliable and robust.

(4) Clinical investigations must be subject to a scientific and ethical review for which—

(a) the ethical review must be performed by an ethics committee;

(b) the Secretary of State must ensure that the procedures for review by ethics committees are compatible with the procedures set out in this Part for the assessment of the application for authorisation of a clinical investigation;

(c) at least one lay person must participate in the ethical review.

(5) A clinical investigation as referred to in paragraph (1) may be conducted only where all of the following conditions are met—

(a) the clinical investigation is the subject of an authorisation by the Secretary of State, in accordance with this Part;

(b) an ethics committee has not issued a negative opinion in relation to the clinical investigation;

(c) the sponsor, or its legal representative or a contact person pursuant to paragraph (2), is established in the United Kingdom;

(d) vulnerable populations and subjects are appropriately protected in accordance with regulations 105 to 108;

(e) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;

(f) unless regulation 108 applies, the subject or, where the subject is not able to give informed consent, the subject's legally designated representative has given informed consent in accordance with regulation 104;

(g) the subject or, where the subject is not able to give informed consent, the subject's legally designated representative, has been provided with the contact details of an entity where further information can be received in case of need;

(h) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning the subject in accordance with the Data Protection Act 2018 are safeguarded;

(i) the clinical investigation has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects, and both the risk threshold and the degree of distress are specifically defined in the clinical investigation plan and constantly monitored;

(j) the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, a qualified dental practitioner or any other authorised health professional entitled to provide the relevant patient care under clinical investigation conditions;

(k) no undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on the subject's legally designated representative, to participate in the clinical investigation;

(l) the investigational device in question—

(i) conforms to the applicable general safety and performance requirements set out in Schedule 3, apart from the aspects covered by the clinical investigation;

(ii) with regard to the aspects covered by the clinical investigation, every precaution has been taken to protect the health and safety of the subjects which includes, where appropriate, technical and biological safety testing and pre-clinical evaluation, as well as provisions in the field of occupational safety and accident prevention, taking into consideration the state of the art;

(m) the requirements of Schedule 15 are fulfilled;

(n) the sponsor, the sponsor's legal representative and as appropriate the investigator must have sufficient insurance (or equivalent financial resources) in place to cover their liability arising from the clinical investigation.

(6) Any subject, or, where the subject is not able to give informed consent, the subject's legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the clinical investigation at any time by revoking his or her informed consent.

(7) Subject to the provisions of the Data Protection Act 2018, the withdrawal of the informed consent in accordance with paragraph (6) must not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.

(8) The investigator must be an authorised health professional qualifying for the role of investigator on account of having the necessary scientific knowledge and experience in patient care and other personnel involved in conducting a clinical investigation must be authorised health professionals in the relevant medical field and in clinical research methodology,

(9) The facilities where the clinical investigation is to be conducted must be suitable for the clinical investigation and must be similar to the facilities where the device is intended to be used.

Informed consent

104.—(1) Informed consent—

(a) must be written, dated and signed by the person performing the interview referred to in paragraph 104(2)(c), and by the subject or, where the subject is not able to give informed consent, the subject's legally designated representative after having been duly informed in accordance with paragraph 104(2);

(b) may, where the subject is unable to write, be given and recorded through appropriate alternative means in the presence of at least one impartial witness and, in that case, the witness must sign and date the informed consent document;

(c) must be documented and a copy of that document or record be provided to the subject or to the subject's legally designated representative;

(d) is only valid if adequate time is given for the subject, or the subject's legally designated representative, to consider his or her decision to participate in the clinical investigation.

(2) Information given to the subject or, where the subject is not able to give informed consent, the subject's legally designated representative, for the purposes of obtaining his or her informed consent must—

(a) enable the subject or the subject's legally designated representative to understand—

(i) the nature, objectives, benefits, implications, risks and inconveniences of the clinical investigation;

(ii) the subject's rights and guarantees regarding his or her protection, in particular the subject's right to refuse to participate in and the right to withdraw from the clinical investigation at any time without any resulting detriment and without having to provide any justification;

(iii) the conditions under which the clinical investigation is to be conducted, including the expected duration of the subject's participation in the clinical investigation;

(iv) the possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical investigation is discontinued;

(b) be kept comprehensive, concise, clear, relevant, and understandable to the subject or his or her legally designated representative;

(c) be provided in a prior interview with a member of the investigating team who is appropriately qualified;

(d) include information about the applicable damage compensation system referred to in regulation 109;

(e) include information about the availability of the clinical investigation results in accordance with paragraph (5).

(3) The information referred to in paragraph (2) must be prepared in writing and be available to the subject or, where the subject is not able to give informed consent, the subject's legally designated representative.

(4) In the interview referred to in paragraph (2)(c)—

(a) special attention must be paid to the information needs of specific patient populations and of individual subjects, as well as to the methods used to give the information; and

(b) the member of the investigating team must ensure that the subject has understood the information.

(5) The subject must be informed that a clinical investigation report and a summary presented in terms understandable to the intended user will be made available irrespective of the outcome of the clinical investigation, and must be informed, to the extent possible, when they have become available.

(6) A minor who is capable of forming an opinion and assessing the information given to him or her, must also assent in order to participate in a clinical investigation.

(7) Where appropriate, this regulation is to be read subject to regulation 108 (Clinical investigations in emergency situations).

Clinical investigations on incapacitated subjects

105.—(1) In the case of incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, a clinical investigation may be conducted only where, in addition to the conditions set out in regulation 103(5), all of the following conditions are met—

(a) unless regulation 108 applies, the informed consent of their legally designated representative has been obtained;

(b) unless regulation 108 applies, the incapacitated subjects have received the information referred to in regulation 104(2) in a way that is adequate in view of their capacity to understand it;

(c) the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to in regulation 104(2) to refuse participation in, or to withdraw from, the clinical investigation at any time, is respected by the investigator;

(d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation;

(e) the clinical investigation is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in clinical investigations on persons able to give informed consent, or by other research methods;

(f) the clinical investigation relates directly to a medical condition from which the subject suffers;

(g) there are scientific grounds for expecting that participation in the clinical investigation will produce a direct benefit to the incapacitated subject outweighing the risks and burdens involved.

(2) The subject, as far as possible, should take part in the informed consent procedure.

Clinical investigations on minors

106. A clinical investigation on minors may be conducted only where, in addition to the conditions set out in regulation 103(5), all of the following conditions are met—

(a) unless regulation 108 applies, the informed consent of their legally designated representative has been obtained;

(b) unless regulation 108 applies, the minors have received the information referred to in regulation 104(2) in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;

(c) the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in regulation 104(2) to refuse participation in, or to withdraw from, the clinical investigation at any time, is respected by the investigator;

(d) no incentives or financial inducements are given to the subject or his or her legally designated representative except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation;

(e) the clinical investigation is intended to investigate treatments for a medical condition that only occurs in minors or the clinical investigation is essential with respect to minors to validate data obtained in clinical investigations on persons able to give informed consent or by other research methods;

(f) the clinical investigation either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;

(g) there are scientific grounds for expecting that participation in the clinical investigation will produce a direct benefit to the minor subject outweighing the risks and burdens involved;

(h) the minor must take part in the informed consent procedure in a way adapted to his or her age and mental maturity;

(i) if, during a clinical investigation, a person reaches the age of 16 years, that person's express informed consent must be obtained before they can continue to participate in the clinical investigation.

Clinical investigations on pregnant or breastfeeding women

107. A clinical investigation on a pregnant or breastfeeding woman may be conducted only where, in addition to the conditions set out in regulation 103(5), all of the following conditions are met—

(a) the clinical investigation has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved;

(b) where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child;

(c) no incentives or financial inducements are given to the subject except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation.

Clinical investigations in emergency situations

108.—(1) Informed consent to participate in a clinical investigation may be obtained, and information on the clinical investigation may be given, after the decision to include the subject in the clinical investigation, provided that decision is taken at the time of the first intervention on the subject in accordance with the clinical investigation plan for that clinical investigation and that all of the following conditions are fulfilled—

(a) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the clinical investigation;

(b) there are scientific grounds to expect that participation of the subject in the clinical investigation will have the potential to produce a direct clinically relevant benefit

for the subject resulting in a measurable health-related improvement alleviating the suffering or improving the health of the subject, or in the diagnosis of its condition;

(c) it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from the subject's legally designated representative;

(d) the investigator certifies that they are not aware of any objections to participate in the clinical investigation previously expressed by the subject;

(e) the clinical investigation relates directly to the subject's medical condition because of which it is not possible, within the therapeutic window, to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the clinical investigation is of such a nature that it may be conducted exclusively in emergency situations;

(f) the clinical investigation poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.

(2) Where paragraph (1) applies, informed consent in accordance with regulation 104 must be sought to continue the participation of the subject in the clinical investigation, and information on the clinical investigation must be given, in accordance with the following requirements—

(a) for incapacitated subjects and minors, the informed consent must be sought by the investigator from his or her legally designated representative without undue delay and the information referred to in regulation 104(2) must be given as soon as possible to the subject and to the subject's legally designated representative;

(b) for all other subjects, the informed consent must be sought by the investigator without undue delay from the subject or the subject's legally designated representative, whichever can be done sooner, and the information referred to in regulation 104(2)must be given as soon as possible to the subject or his or her legally designated representative, as applicable.

(3) For the purposes of paragraph (2)(b), where informed consent has been obtained from the legally designated representative, informed consent to continue the participation in the clinical investigation must be obtained from the subject as soon as the subject is capable of giving informed consent.

(4) Where consent is not given, the subject or, where applicable, the subject's legally designated representative must be informed of the right to object to the use of data obtained from the clinical investigation.

Damage compensation

109. Sponsors must, taking account of the risk class of a device, the type of device and the size of the enterprise, hold sufficient insurance (or equivalent financial resources) to meet any potential financial liability arising from damage caused by a clinical investigation.

Application for clinical investigations

110.—(1) The sponsor of a clinical investigation must submit an application to the Secretary of State accompanied by the documentation referred to in Chapter II of Schedule 15.

(2) Within 10 days of receiving the application, the Secretary of State must notify the sponsor as to whether the clinical investigation falls within the scope of this Part and as to whether the application dossier is complete in accordance with Chapter II of Schedule 15.

(3) Within one week of any change occurring in relation to the documentation referred to in Chapter II of Schedule 15, the sponsor must—

(a) up-date the relevant data;

(b) make that change to the documentation clearly identifiable;

(c) notify the Secretary of State of the update.

(4) Where the Secretary of State finds that the clinical investigation applied for does not fall within the scope of this Part or that the application dossier is not complete, the Secretary of State must inform the sponsor and must set a time limit of maximum 10 days for the sponsor to comment, but the Secretary of State may extend this period by a maximum of 20 days where appropriate.

(5) Where—

(a) the sponsor has not provided comments within the time limit referred to in the paragraph (4), the application must be deemed to have lapsed;

(b) the sponsor considers the application does fall under the scope of this Part or is complete but the Secretary of State does not agree, the application must be considered to have been rejected.

(6) The Secretary of State must notify the sponsor within 5 days of receipt of the comments or of the requested additional information, whether the clinical investigation is considered as falling within the scope of this Part or that the application is complete.

(7) The Secretary of State may extend the notification periods referred to in paragraphs (2) and (6) each by a further 5 days.

(8) The validation date of the application is to be considered—

(a) the date on which the sponsor is notified in accordance with paragraphs (2) and (6); or

(b) where the sponsor is not notified, the last day of the periods referred to in paragraph (4).

(9) The sponsor may start a clinical investigation in the following circumstances—

(a) in the case of —

(i) investigational Class I devices or non-invasive Class IIa and Class IIb devices, immediately after the validation date of the application pursuant to paragraph (8); or

(ii) investigational devices, other than those referred to in paragraph (i) as soon as the Secretary of State has notified the sponsor of the Secretary of State's authorisation; and

(b) in both cases, provided a negative opinion has not been issued by an ethics committee in the United Kingdom in respect of the clinical investigation.

(10) For the purposes of paragraph (9)(a)(ii), the Secretary of State must notify the sponsor of the authorisation within 45 days of the validation date referred to in paragraph (8) and the Secretary of State may extend this period by a further 20 days for the purpose of consulting with experts.

Assessment by Secretary of State

111.—(1) The Secretary of State must ensure that the persons validating and assessing the clinical investigation application, or deciding on it do not have conflicts of interest and in particular are—

(a) independent of—

(i) the sponsor;

(ii) the investigators involved;

(iii) the person financing the clinical investigation; and

(b) free of any undue influence.

(2) The Secretary of State must ensure that the assessment is done jointly by an appropriate number of persons who collectively have the necessary qualifications and experience.

(3) The Secretary of State—

(a) must assess whether the clinical investigation is designed in such a way that potential remaining risks to subjects or third persons, after risk minimization, are justified, when weighed against the clinical benefits to be expected;

(b) must, while taking into account applicable designated standards, examine in particular—

(i) the demonstration of compliance of the investigational device with the applicable general safety and performance requirements, apart from the aspects covered by the clinical investigation, and whether, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects and this includes, where appropriate, assurance of technical and biological safety testing and pre-clinical evaluation;

(ii) whether the risk-minimisation solutions employed by the sponsor are described in designated standards and, in those cases where the sponsor does not use those standards, whether the risk-minimisation solutions provide a level of protection that is equivalent to that provided by those designated standards;

(iii) whether the measures planned for the safe installation, putting into service and maintenance of the investigational device are adequate;

(iv) the reliability and robustness of the data generated in the clinical investigation, taking account of statistical approaches, design of the investigation and methodological aspects, including sample size, comparator and endpoints;

(v) whether the requirements of Schedule 15 are met;

(vi) in the case of devices for sterile use, evidence of the validation of the manufacturer's sterilisation procedures or information on the reconditioning and sterilisation procedures which have to be conducted by the investigation site;

(vii) the demonstration of the safety, quality and usefulness of any components of animal or human origin or of substances, which may be considered medicinal products in accordance with the Human Medicines Regulations 2012.

(4) The Secretary of State must refuse the authorisation of the clinical investigation if—

(a) the application dossier submitted remains incomplete;

(b) the device or the submitted documents, especially the investigation plan and the investigator's brochure, do not correspond to the state of scientific knowledge, and the clinical investigation, in particular, is not suitable for providing evidence for the safety, performance characteristics or benefit of the device on subjects or patients;

(c) the requirements of regulation 103 (General requirements for clinical investigations conducted to demonstrate the conformity of devices) are not met; or

(d) any assessment under paragraph (3) is negative.

Appeal rights relating to regulations 110 and 111

112.—(1) Where the sponsor is dissatisfied with a decision taken by the Secretary of State under regulation 110(6) or regulation 111(4), the sponsor or the sponsor's legal representative in the United Kingdom may require the Secretary of State to seek advice from such person as the Institute determines as to—

(a) whether the clinical investigation falls within this Part; or

(b) whether the Secretary of State correctly refused the authorisation.

(2) Where the sponsor acts in accordance with paragraph (1), the sponsor is responsible for the fees, costs and expenses of the Institute and of the person appointed by the Institute.

(3) In this regulation, "Institute" means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.

Conduct of a clinical investigation

113.—(1) The sponsor and the investigator must ensure that the clinical investigation is conducted in accordance with the approved clinical investigation plan.

(2) The sponsor—

(a) must ensure adequate monitoring of the conduct of the clinical investigation in order to—

(i) verify that the rights, safety and wellbeing of the subjects are protected;

(ii) that the reported data are reliable and robust;

(iii) that the conduct of the clinical investigation is in compliance with the requirements of this Part;

(b) must determine the extent and nature of the monitoring on the basis of an assessment taking into consideration all the characteristics of the clinical investigation including the following—

(i) the objective and methodology of the clinical investigation;

(ii) the degree of deviation of the intervention from normal clinical practice.

(3) All clinical investigation information must be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the Data Protection Act 2018.

(4) Appropriate technical and organisational measures must be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves transmission over a network.

(5) The Secretary of State must inspect, at an appropriate level, investigation sites to check that clinical investigations are conducted in accordance with the requirements of this Part and with the approved investigation plan.

(6) The sponsor must establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the investigation.

Clinical investigations regarding devices bearing a CE marking within the intended purpose of those devices

114.—(1) Where—

(a) a clinical investigation is to be conducted to further assess, within the scope of its intended purpose, a device which already bears the CE marking in accordance with regulation 85, ('PMCF investigation'); and

(b) the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome,

the sponsor must notify the Secretary of State at least 30 days prior to its commencement.

(2) The sponsor must include documentation referred to in Chapter II of Schedule 15 as part of the notification.

(3) The following provisions apply to PMCF investigations—

(a) sub-paragraphs (b) to (k) and (m) of regulation 103(5);

(b) regulations 116 to 118;

(c) regulation 119(6);

(d) the relevant provisions of Schedule 15.

Clinical investigations regarding devices bearing a CE marking outside the intended purpose of those devices

115. Regulations 103 to 120 apply where a clinical investigation is to be conducted to assess, outside the scope of its intended purpose, a device which already bears the CE marking in accordance with regulation 85.

Substantial modifications to clinical investigations

116.—(1) If a sponsor intends to introduce modifications to a clinical investigation that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, the sponsor must—

(a) within one week of deciding to introduce modifications, notify the Secretary of State of the reasons for and the nature of those modifications;

(b) include an updated version of the relevant documentation referred to in Chapter II of Schedule 15 as part of the notification;

(c) ensure that changes to the relevant documentation are clearly identifiable.

(2) The Secretary of State must assess any substantial modification to the clinical investigation in accordance with the procedure laid down in regulation 111.

(3) The sponsor may implement the modifications referred to in paragraph (1) at the earliest 38 days after the notification referred to in that paragraph, unless—

(a) the Secretary of State has notified the sponsor of the Secretary of State's refusal based on the grounds referred to in regulation 111(4) or on considerations of public health, subject and user safety or health, of public policy, or

(b) an ethics committee has issued a negative opinion in relation to the substantial modification to the clinical investigation.

(4) The Secretary of State may extend the period referred to in paragraph (3) by a further 7 days, for the purpose of consulting with experts.

Corrective measures to be taken by the Secretary of State

117.—(1) Where the Secretary of State has grounds for considering that the requirements set out in this Part are not met, the Secretary of State may take any of the following measures—

(a) revoke the authorisation for the clinical investigation;

(b) suspend or terminate the clinical investigation;

(c) require the sponsor to modify any aspect of the clinical investigation.

(2) Before the Secretary of State takes any of the measures referred to in paragraph (1), the Secretary of State must, except where immediate action is required, ask the sponsor or the investigator or both for their opinion which must be delivered within 7 days.

Information from the sponsor at the end of a clinical investigation or in the event of a temporary halt or early termination

118.—(1) Subject to paragraph (2), if the sponsor has temporarily halted a clinical investigation or has terminated a clinical investigation early, the sponsor must inform the Secretary of State within 15 days of the temporary halt or early termination, providing a justification for that halt or termination.

(2) Where the sponsor has temporarily halted the clinical investigation or terminated early it early on safety grounds, the sponsor must inform the Secretary of State of that halt or termination within 24 hours.

(3) The end of a clinical investigation is deemed to coincide with the last visit of the last subject unless another point in time for such end is set out in the clinical investigation plan.

(4) The sponsor must notify the Secretary of State of the end of a clinical investigation and that notification must be made within 15 days of the end of the clinical investigation.

(5) Irrespective of the outcome of the clinical investigation but subject to paragraph (7), within one year of the end of the clinical investigation or within 3 months of the early termination or temporary halt, the sponsor must submit to the Secretary of State a clinical investigation report as referred to in paragraph 2(8) of Chapter I and paragraph 7 of Chapter III of Schedule 15.

(6) The clinical investigation report must—

(a) be accompanied by a summary presented in terms that are easily understandable to the intended user;

(b) be submitted by the sponsor to the Secretary of State along with that summary.

(7) Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year of the end of the investigation, it must—

(a) be submitted as soon as it is available;

(b) specify in the clinical investigation plan, referred to in paragraph 3 of Chapter II of Schedule 15, when the results of the clinical investigation are going to be

available, together with a justification for why the report cannot be submitted within one year of the end of the investigation.

(8) The Secretary of State–

(a) may issue guidelines regarding the content and structure of the summary of the clinical investigation report;

(b) may issue guidelines for the formatting and sharing of raw data, for cases where the sponsor decides to share raw data on a voluntary basis (and may take as a basis and adapt, where possible, existing guidelines for sharing of raw data in the field of clinical investigations).

(9) The summary and the clinical investigation report referred to in paragraph (6) must—

(a) in circumstances other than those provided for in sub-paragraphs (b) and (c), be made publicly accessible, at the latest when the device is registered in accordance with regulation 93 and before it is placed on the market;

(b) in cases of early termination or temporary halt, become publicly accessible immediately after submission; or

(c) if the device is not registered in accordance with regulation 93, become publicly accessible within one year of the summary and the report having been submitted pursuant to paragraph (5).

Recording and reporting of adverse events that occur during clinical investigations

119.—(1) The sponsor must fully record all of the following—

(a) any adverse event of a type identified in the clinical investigation plan as being critical to the evaluation of the results of that clinical investigation;

(b) any serious adverse event;

(c) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(d) any new findings in relation to any event referred to in sub-paragraphs (a) to (c);

(2) The sponsor must report, without delay (but having regard to paragraph (3)), to the Secretary of State, all of the following—

(a) any serious adverse event that has a causal relationship with the investigational device, the comparator or the investigation procedure or where such causal relationship is reasonably possible;

(b) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(c) any new findings in relation to any event referred to in sub-paragraphs (a) and (b).

(3) The period for reporting must take account of the severity of the event and, where necessary to ensure timely reporting, the sponsor may submit an initial report that is incomplete followed up by a complete report.

(4) Upon request by the Secretary of State, the sponsor must provide all information referred to in paragraph (1).

(5) The sponsor must also report to the Secretary of State any event referred to in paragraph (2) that occurred in a country outside the United Kingdom in which a clinical investigation is performed under the same clinical investigation plan as the one applying to a clinical investigation covered by this Part.

(6) This regulation does not apply to PMCF investigations referred to in regulation 114 but the provisions on vigilance provided for in regulations 125 to 128 apply instead of this regulation.

Requirements regarding other clinical investigations

120.—(1) Clinical investigations, not performed pursuant to any of the purposes listed in regulation 103(1), must comply with the provisions of regulation 103(2) to 103(3), sub-paragraphs (b), (c), (d), (f), (h), and (l) of regulation 103(5) and regulation 103(8).

(2) In order to protect the rights, safety, dignity and well-being of subjects and the scientific and ethical integrity of clinical investigations not performed for any of the purposes listed in regulation 103(1), Secretary of State may by regulations define any additional requirements for such investigations.

POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

Post-market surveillance

Post-market surveillance system of the manufacturer

121.—(1) For each device, manufacturers must plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device and that system must be an integral part of the manufacturer's quality management system referred to in regulation 76(14).

(2) The post-market surveillance system must be suited to—

(a) actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime;

(b) drawing the necessary conclusions;

(c) determining, implementing and monitoring any preventive and corrective actions.

(3) The manufacturer must ensure that—

(a) data gathered by the manufacturer's post-market surveillance system is used in particular—

(i) to update the benefit-risk determination and to improve the risk management as referred to in Part 1 of Schedule 3;

(ii) to update the design and manufacturing information, the instructions for use and the labelling;

(iii) to update the clinical evaluation;

(iv) to update the summary of safety and clinical performance referred to in regulation 96;

(v) for the identification of needs for preventive, corrective or field safety corrective action;

(vi) for the identification of options to improve the usability, performance and safety of the device;

(vii) when relevant, to contribute to the post-market surveillance of other devices;

(viii) to detect and report trends in accordance with regulation 126;

(b) the technical documentation is updated accordingly.

(4) If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer must—

(a) implement the appropriate measures and inform the Secretary of State and, where applicable, the notified body;

(b) where a serious incident is identified or a field safety corrective action is implemented, report that incident in accordance with regulation 125.

Post-market surveillance plan

122. The post-market surveillance system referred to in regulation 121 must be based on a post-market surveillance plan, the requirements for which are set out in paragraph 1(2) of Schedule 5 and, for devices other than custom-made devices, the post-market surveillance plan must be part of the technical documentation specified in Schedule 4.

Post-market surveillance report

123.—(1) Manufacturers of Class I devices must prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in regulation 122 together with a rationale and description of any preventive and corrective actions taken.

(2) The report must be updated when necessary and made available to the Secretary of State upon request.

Periodic safety update report

124.—(1) Manufacturers of Class IIa, Class IIb and Class III devices must prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in regulation 122 together with a rationale and description of any preventive and corrective actions taken.

(2) Throughout the lifetime of the device concerned, that PSUR must set out—

(a) the conclusions of the benefit-risk determination;

(b) the main findings of the PMCF;

(c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

(3) Manufacturers of Class IIb and Class III devices must—

(a) update the PSUR at least annually;

(b) ensure that, except in the case of custom-made devices, the is part of the technical documentation as specified in Schedules 4 and 5.

(4) Manufacturers of Class IIa devices must—

(a) update the PSUR when necessary and at least every 2 years;

(b) ensure that, except in the case of custom-made devices, the PSUR is part of the technical documentation as specified in Schedules 4 and 5.

(5) For custom-made devices, the PSUR must be part of the documentation referred to in paragraph 12(2) of Schedule 13.

(6) For Class III or implantable devices a manufacturer must—

(a) submit the PSUR to the notified body involved in the conformity assessment;

(b) make available to the Secretary of State the evaluation of the PSUR made by the notified body.

(7) For devices other than Class III devices a manufacturer must—

(a) make the PSUR available to the notified body involved in the conformity assessment;

(b) upon request by the Secretary of State, make the PSUR available to the Secretary of State.

Reporting of serious incidents and field safety corrective actions

125.—(1) Manufacturers of devices made available on the market, other than investigational devices, must report, to the Secretary of State the following—

(a) any serious incident involving devices made available on the market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to regulation 126;

(b) any field safety corrective action in respect of devices made available on the market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

(2) The period for the reporting referred to in paragraph (1) must take account of the severity of the serious incident.

(3) Subject to paragraphs (4) and (5), manufacturers must report any serious incident as referred to in paragraph (1)(a) immediately after they have established the causal relationship between that incident and their device, or that such causal relationship is reasonably possible, and not later than 15 days after they become aware of the incident.

(4) In the event of a serious public health threat, the report referred to in paragraph (1) must be provided not later than 2 days after the manufacturer becomes aware of the threat.

(5) In the event of death or an unanticipated serious deterioration in a person's state of health, the report must be provided immediately after the manufacturer has established or as soon as it suspects a causal relationship between the device and the serious incident but not later than 10 days after the date on which the manufacturer becomes aware of the serious incident.

(6) Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.

(7) If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it must nevertheless submit a report within the timeframe required in accordance with paragraphs (2) to (5).

(8) Except in cases of urgency in which the manufacturer needs to undertake field safety corrective action immediately, the manufacturer must, without undue delay, report the field safety corrective action referred to in paragraph (1)(b) in advance of the field safety corrective action being undertaken.

(9) For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide

periodic summary reports instead of individual serious incident reports, on condition that the Secretary of State, has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

(10) The Secretary of State must—

(a) take appropriate measures such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the Secretary of State suspected serious incidents referred to in paragraph (1)(a);

(b) record reports received from healthcare professionals, users and patients.

(11) Where the Secretary of State obtains such reports on suspected serious incidents referred to in paragraph (1)(a) from healthcare professionals, users or patients, the Secretary of State must take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.

(12) Where the manufacturer of the device concerned considers that an incident is a serious incident, it must provide a report in accordance with paragraphs (1) to (5) on that serious incident to the Secretary of State and must take the appropriate follow-up action in accordance with regulation 127.

(13) Where—

(a) the manufacturer of the device considers that an incident is not a serious incident or is an expected undesirable side-effect which will be covered by trend reporting in accordance with regulation 126, the manufacturer must provide an explanatory statement;

(b) the Secretary of State does not agree with the conclusion of the explanatory statement, the Secretary of State may require the manufacturer—

(i) to provide a report in accordance with paragraphs (1) to (5);

(ii) to ensure that appropriate follow-up action is taken in accordance with regulation 127.

Trend reporting

126.—(1) Manufacturers must report to the Secretary of State any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in paragraphs (1) and (5) of Schedule 3 and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.

(2) The significant increase must be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices in question, during a specific period as specified in the technical documentation and product information.

(3) The manufacturer must specify how to manage the incidents referred to in paragraph (1) and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period, in the post-market surveillance plan referred to in regulation 122.

(4) The Secretary of State may conduct assessments on the trend reports referred to in paragraph (1) and require the manufacturer to adopt appropriate measures in accordance with this Part in order to ensure the protection of public health and patient safety.

Analysis of serious incidents and field safety corrective actions

127.—(1) Following the reporting of a serious incident pursuant to regulation 125(1), a manufacturer must—

(a) without delay, perform the necessary investigations in relation to the serious incident and the devices concerned;

(b) include a risk assessment of the incident and field safety corrective action taking into account criteria as referred to in paragraph (4)(a) as appropriate.

(2) A manufacturer must—

(a) cooperate with the Secretary of State during the investigations referred to in paragraph (1);

(b) not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the Secretary of State of such action.

(3) The Secretary of State must take the necessary steps to ensure that any information regarding a serious incident that has occurred, or a field safety corrective action that has been or is to be undertaken, and that is brought to the Secretary of State's knowledge in accordance with regulation 125, is evaluated, if possible together with the manufacturer and, where relevant the notified body concerned.

(4) For the purposes of the evaluation referred to in paragraph (3), the Secretary of State must evaluate—

(a) the risks arising from the reported serious incident and evaluate any related field safety corrective actions, taking into account the protection of public health and criteria such as—

(i) causality, detectability and probability of recurrence of the problem;

(ii) frequency of use of the device;

(iii) probability of occurrence of direct or indirect harm;

(iv) the severity of that harm;

(v) the clinical benefit of the device;

(vi) the intended and potential users;

(vii) the population affected;

(b) the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for, and kind of, any other corrective action, in particular taking into account the principle of inherent safety contained in Schedule 3.

(5) Upon request by the Secretary of State, manufacturers must provide all documents necessary for the risk assessment.

(6) The Secretary of State must monitor the manufacturer's investigation of a serious incident and where necessary, the Secretary of State may intervene in a manufacturer's investigation or initiate an independent investigation.

(7) A manufacturer must provide a final report to the Secretary of State setting out its findings from the investigation which must set out conclusions and where relevant indicate corrective actions to be taken.

(8) In the case of devices referred to in regulation 68(8) and where the serious incident or field safety corrective action may be related to a substance which, if used separately, would be considered to be a medicinal product, the Secretary of State must ensure that those

responsible for licensing medicinal products are informed of that serious incident or field safety corrective action.

(9) In the case of —

(a) devices referred to in regulation 68(6)(h);

(b) devices falling under regulation 68(14),

and where the serious incident or field safety corrective action may be related to the derivatives of tissues or cells of human origin utilised for the manufacture of the device, the Secretary of State must inform the Human Tissue Authority.

(10) A manufacturer must ensure that information about the field safety corrective action taken—

(a) is brought without delay to the attention of users of the device in question by means of a field safety notice;

(b) except in cases of urgency, the content of the draft field safety notice must be submitted to the Secretary of State to allow the Secretary of State to make comments.

(11) The field safety notice must—

(a) allow the correct identification of the device or devices involved;

(b) explain, in a clear manner, without understating the level of risk, the reasons for the field safety corrective action with reference to the device malfunction and associated risks for patients, users or other persons;

(c) clearly indicate all the actions to be taken by users;

(d) be accessible to the public.

Analysis of vigilance data

128.—(1) The Secretary of State must put in place systems and processes to actively monitor the data available, in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

(2) Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the Secretary of State must inform the manufacturer, or where applicable the UK responsible person, which must then take the necessary corrective actions.

Electronic system on vigilance and on post market surveillance

129.—(1) The Secretary of State must set up and manage an electronic system to collate and process the following information—

(a) the reports by manufacturers on serious incidents and field safety corrective actions;

(b) the periodic summary reports by manufacturers;

(c) the reports by manufacturers on trends;

(d) the PSURs;

(e) the field safety notices by manufacturers.

(2) The Secretary of State must ensure that healthcare professionals and the public receive appropriate information contained in the electronic system referred to in paragraph (1).

(3) The Secretary of State—

(a) may make arrangements with other countries or international organisations for the purpose of granting access (at an appropriate level) to the electronic system referred to in paragraph (1);

(b) must only make any such arrangements on the basis of reciprocity;

(c) must base any such arrangements on data protection rules equivalent to those applicable in the United Kingdom.

Market surveillance

Market surveillance activities

130.—(1) The Secretary of State must—

(a) perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples;

(b) take account of established principles regarding risk assessment and risk management, vigilance data and complaints.

(2) The Secretary of State must—

(a) draw up an annual surveillance activity plan;

(b) allocate a sufficient number of material and competent human resources in order to carry out those activities.

(3) In order to fulfil the obligations laid down in paragraph (1), the Secretary of State—

(a) may require economic operators to make available the documentation and information necessary for the purpose of carrying out those activities and, where justified, to provide the necessary samples of devices or access to devices free of charge;

(b) must carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, suppliers or subcontractors, and, where necessary, at the facilities of professional users.

(4) The Secretary of State must prepare and publish an annual summary of the results of surveillance activity.

(5) The Secretary of State may confiscate, destroy or otherwise render inoperable devices that present an unacceptable risk or are falsified devices where the Secretary of State deems it necessary to do so in the interests of the protection of public health.

(6) Following each inspection carried out for the purposes referred to in paragraph (1), the Secretary of State must—

(a) draw up a report on the findings of the inspection that concern compliance with the legal and technical requirements applicable under this Part;

(b) set out in the report any corrective actions needed.

(7) The Secretary of State must—

(a) communicate the content of the report referred to in paragraph (6) to the economic operator that has been the subject of the inspection;

(b) before adopting the final report, give that economic operator the opportunity to submit comments.

(8) The Secretary of State must—

(a) at least every 4 years, review and assess the functioning of market surveillance activities;

(b) make a summary of the results accessible to the public.

(9) Where appropriate, the Secretary of State must cooperate with the authorities of third countries with a view to exchanging information, providing technical support and promoting activities relating to market surveillance.

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

131. Where the Secretary of State, based on data obtained by vigilance or market surveillance activities or on other information, has reason to believe that a device—

(a) may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health; or

(b) otherwise does not comply with the requirements laid down in this Part,

the Secretary of State must carry out an evaluation covering all requirements laid down in this Part relating to the risk presented by the device, or to any other non-compliance of the device and the relevant economic operators must cooperate with the Secretary of State.

Procedure for dealing with devices presenting an unacceptable risk to health and safety

132.—(1) Where, having performed an evaluation pursuant to regulation 131, the Secretary of State finds that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, the Secretary of State must—

(a) without delay, require a manufacturer of the devices, and all other relevant economic operators established in the United Kingdom, to take all appropriate and duly justified corrective action to bring the device into compliance with the requirements of this Part relating to the risk presented by the device;

(b) in a manner that is proportionate to the nature of the risk, restrict the making available of the device on the market, subject the making available of the device for specific requirements, withdraw the device from the market, or recall it, within a reasonable period that is clearly defined and communicated to the relevant economic operator.

(2) The economic operators as referred to in paragraph (1) must, without delay, ensure that all appropriate corrective action is taken throughout the United Kingdom in respect of all the devices concerned that they have made available on the market.

(3) Where the economic operator as referred to in paragraph (1) does not take adequate corrective action within the period referred to in paragraph (1), the Secretary of State must take all appropriate measures to prohibit or restrict the making available of the device on the market, to withdraw the device or to recall it.

Other non-compliance

133.—(1) Where, having performed an evaluation pursuant to regulation 131, the Secretary of State finds that a device does not comply with the requirements laid down in this Part but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, the Secretary of State must require the relevant economic operator to bring the non-compliance concerned to an

end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non- compliance.

(2) Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph (1), the Secretary of State must, without delay, take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market.

Preventive health protection measures

134. Where the Secretary of State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices, considers that, in order to protect the health and safety of patients, users or other persons or other aspects of public health, the making available on the market or putting into service of a device or a specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled, the Secretary of State may take any necessary and justified measures in accordance with Part VII of these Regulations or under relevant consumer protection legislation.

Regulations

135.—(1) Regulations under this Part may—

(a) make different provision for different purposes or different areas;

(b) make consequential, incidental, transitional or supplemental provision.

(2) A power to make regulations under this Part is exercisable by the Secretary of State by statutory instrument.

(3) A statutory instrument which contains regulations under this Part is subject to annulment in pursuance of a resolution of each House of Parliament.”.