STATUTORY INSTRUMENTS

2019 No. 791

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

PART 3

New part IX of the Medical Devices Regulations

11. After regulation 135 (as inserted by regulation 10) insert—

"PART IX

The rights, powers, liabilities, obligations, restrictions, remedies and procedures recognised under the in vitro diagnostic Medical Devices Regulation (see regulation 4P)

Scope and definitions

Subject matter and scope

136.—(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) in vitro diagnostic medical devices for human use; and

(b) accessories to such medical devices.

(2) This Part also applies to performance studies concerning in vitro diagnostic medical devices and accessories to such devices.

(3) For the purposes of this Part and Schedules 17 to 28 in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices are referred to as 'devices'.

(4) This Part does not apply to—

(a) relevant devices placed on the market in accordance with Part IV;

(b) products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;

(c) invasive sampling products or products which are directly applied to the human body for the purpose of obtaining a specimen;

(d) internationally certified reference materials;

(e) materials used for external quality assessment schemes.

(5) Any device which, when placed on the market or put into service, incorporates, as an integral part, a medical device as defined in regulation 69 is governed by Part VIII, but the requirements of this Part apply to the in vitro diagnostic medical device part.

(6) Where a device is also machinery within the meaning of the Supply of Machinery (Safety) Regulations 2008(**1**) and where—

(a) a hazard under that legislation exists;

(b) the provisions of that legislation are more specific than the general safety and performance requirements set out in Schedule 17,

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

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

(8) 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.

(9) 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 devices on a medical prescription;

(b) requirements relating to—

(i) the dispensing of devices by certain health professionals or health care institutions; use certain devices;

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

(10) This Part does not restrict the freedom of the press or freedom of expression.

Definitions

137. In this Part and Schedules 17 to 28—

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

"adverse event" means any untoward medical occurrence, inappropriate patient management decision, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a performance study, whether or not related to the device for performance study;

"analytical performance" means the ability of a device to correctly detect or measure a particular analyte;

"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) 2017/746;

(**1**) S.I. 2008/1597.

"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;

"calibrator" means a measurement reference material used in the calibration of a device;

"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 other applicable legislation providing for its affixing;

"clinical benefit" means the positive impact of a device related to its function, such as that of screening, monitoring, diagnosis or aid to diagnosis of patients, or a positive impact on patient management or public health;

"clinical evidence" means clinical data and performance evaluation results, pertaining to a device of a sufficient number 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 performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user;

"common specifications" or "CS" must be construed in accordance with regulation 144;

"companion diagnostic" means device which is essential for the safe and effective use of a corresponding medicinal product to—

(a) identify, before or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or

(b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product;

"compatibility" is 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 adaption 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 relating to a device have been fulfilled;

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

"control material" means a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of a device;

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

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

"device deficiency" in relation to a device for performance study, means any inadequacy in its identity, quality, durability, reliability, safety or performance

including malfunction, use errors or inadequacy in information supplied by the manufacturer;

"device for near-patient testing" means any device that is not intended for self-testing but is intended to perform testing outside the laboratory environment, generally near to, or at the side of, the patient by a health professional;

"device for performance study" means a device intended by the manufacturer to be used in a performance study but does not include a device intended to be used for research purposes with no medical objective;

"device for self-testing" means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services;

"diagnostic sensitivity" means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;

"diagnostic specificity" means the ability of a device to recognise the absence of a target marker associated with a particular disease or condition;

"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 into service;

"economic operator" means a manufacturer, an authorised representative, a UK responsible person, an importer or a distributor;

"ethics committee" means an independent body established or recognised under the Care Act 2014;

"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 any non-compliance is unintentional;

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

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

"fully refurbishing" for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or 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 the primary purpose of which is the care or treatment of patients or the promotion of public health;

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

"incident" in relation to a device made available on the market, means—

(a) any malfunction or deterioration in its characteristics or performance, including use-error due to its ergonomic features and any inadequacy in the information supplied by the manufacturer;

(b) any harm as a consequence of a medical decision; or

(c) action taken or not taken on the basis of information or results provided by the device;

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

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

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

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

(b) the instructions for use; or

(c) the promotional or sales materials or statements or as specified by the manufacturer in the performance evaluation;

"interoperability" is the ability of 2 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;

"interventional clinical performance study" means a clinical performance study where the test results may influence patient management decisions or may be used to guide treatment;

"investigator" means an individual responsible for the conduct of a performance study at a performance study site;

"in vitro diagnostic medical device" means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following—

(a) concerning a physiological or pathological process or state;

(b) concerning congenital physical or mental impairments;

(c) concerning the predisposition to a medical condition or a disease;

(d) to determine the safety and compatibility with potential recipients;

(e) to predict treatment response or reactions;

(f) to define or monitor therapeutic measures; and

specimen receptacles must also be deemed to be in vitro diagnostic medical devices;

"kit" means a set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic examination;

"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 a relevant field of healthcare or medical discipline;

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

"likelihood ratio" means the likelihood of a given result arising in an individual with the target clinical condition or physiological state compared to the likelihood of the same result arising in an individual without that clinical condition or physiological state;

"making available on the market" means any supply of a device, other than a device for performance study, 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;

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

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

"medical device" has the same meaning as in regulation 69;

"negative predictive value" means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;

"notified body" means a conformity assessment body designated in accordance with Regulation (EU) 2017/746;

"performance of a device" means the ability of a device to achieve its intended purpose as claimed by the manufacturer and consists of the analytical and, where applicable, the clinical performance supporting that intended purpose;

"performance evaluation" means an assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device;

"performance study" means a study undertaken to establish or confirm the analytical or clinical performance of a device;

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

"placing on the market" means the first making available of a device, other than a device for performance study, on the United Kingdom market;

"positive predictive value" means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;

"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 purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

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

"predictive value" means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;

"putting into service" means the making available of a device, other than a device for performance study, to the final user as being ready for use on the United Kingdom market for the first time for its intended purpose;

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

"Regulation (EU) 2017/746" means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5th April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU(**2**) as it has effect in European Union Law;

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

"scientific validity of an analyte" means the association of an analyte with a clinical condition or a physiological state;

"serious adverse event" means any adverse event that led to any of the following—

(a) a patient management decision resulting in death or an imminent life-threatening situation for the individual being tested, or in the death of the individual's offspring;

(b) death;

(c) serious deterioration in the health of the individual being tested or the recipient of tested donations or materials, that resulted in any of the following—

  (i) life-threatening illness or injury;

  (ii) permanent impairment of a body structure or a body function;

  (iii) hospitalisation or prolongation of patient hospitalisation;

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

  (v) chronic disease;

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

"serious incident" means any 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;

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

(c) serious public health threat;

"serious public health threat" means an event which could result in imminent risk of death, serious deterioration in a 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 and time;

(**2**) OJNo. L 117 5.5.2017, p.176

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

"specimen receptacle" means a device, whether of a vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination;

"sponsor" means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the performance study;

"subject" means an individual who participates in a performance study and whose specimens undergo in vitro examination by a device for performance study or by a device used for control purposes;

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

"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 22;

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

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

Regulatory status of products

138.—(1) Subject to paragraph (2), the Secretary of State may by regulations determine whether or not a specific product, category or group of products, falls within the definition of an in vitro diagnostic medical device or an accessory to an in vitro diagnostic medical device.

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

Genetic information, counselling and informed consent

139. The Secretary of State must ensure that where a genetic test is used on individuals, in the context of healthcare and for the medical purposes of diagnostics, improvement of treatment, predictive or prenatal testing—

(a) the individual being tested or, where applicable, his or her legally designated representative is provided with relevant information on the nature, the significance and the implications of the genetic test, as appropriate;

(b) subject to paragraph (2), there is appropriate access to counselling in the case of the use of genetic tests that provide information on the genetic predisposition for medical conditions or diseases which are generally considered to be untreatable according to the state of science and technology.

(2) Paragraph (1)(b) does not apply in cases where a diagnosis of a medical condition or a disease which the individual being tested is already known to have is confirmed by a genetic test or in cases where a companion diagnostic is used.

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

Placing on the market and putting into service

140.—(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 17 which apply to it, taking into account its intended purpose.

(3) Demonstration of conformity with the general safety and performance requirements must include a performance evaluation in accordance with regulation 167.

(4) Devices that are manufactured and used within health institutions, with the exception of devices for performance studies, must be considered as having been put into service.

(5) With the exception of the relevant general safety and performance requirements set out in Schedule 17, the requirements of this Part do not apply to a device which is manufactured and used only within a health institution, provided that all of the following conditions are met—

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

(b) manufacture and use of the devices occur under appropriate quality management systems;

(c) the laboratory of the health institution is compliant with standard EN ISO 15189 and, where applicable, provisions regarding accreditation;

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

(e) 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 device to the Secretary of State;

(f) the health institution draws up a declaration which it must make publicly available, including—

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

(ii) the details necessary to identify the devices;

(iii) a declaration that the device meets the general safety and performance requirements set out in Schedule 17 and, where applicable, information on which requirements are not fully met and a reasoned justification for not meeting those requirements;

(g) for Class D devices (and for other classes of device in accordance with the rules set out in Schedule 23) 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 that the general safety and performance requirements set out in Schedule 17 are met;

(h) the Secretary of State may apply the provisions of sub-paragraph (g) also to Class A, B or C devices in accordance with the rules set out in Schedule 23;

(i) the health institution must take all necessary measures to ensure that all devices are manufactured in accordance with the document referred to in sub-paragraph (g);

(j) the health institution reviews experience gained from 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 submit to the Secretary of State any further relevant information about such devices which it has manufactured and used.

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

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

Distance sales

141.—(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) 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 9th September 2015 (as it has effect in European Union Law).

Claims

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

(a) ascribing functions and properties to the 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 standards

143.—(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 which cover those designated 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, performance studies, clinical evaluation or post-market performance follow-up ('PMPF').

Common specifications

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

(a) adopted by the European Commission in accordance with the procedure set down in Article 9(1) of Regulation (EU) 2017/746;

(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 and designated in accordance with paragraph (1) or specified in regulations made under paragraph (5) 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 and designated 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 the CS to the attention of any person who may have an interest in the CS.

(5) The Secretary of State may cancel the designation by removing from publication the reference to the CS published in accordance with paragraph (1)(b) and, where he does 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 designate it in accordance with paragraph (1)(b).

General obligations of manufacturers

145.—(1) When placing their 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 17.

(3) Manufacturers must conduct a performance evaluation in accordance with the requirements set out in regulation 167 and Schedule 27, including a PMPF.

(4) Manufacturers must draw up and keep up to date the technical documentation for their devices.

(5) The technical documentation mentioned 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 18 and 19.

(6) Where the Secretary of State considers it necessary in the light of technical progress, the Secretary of State may by regulations amend Schedules 18 and 19.

(7) Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than devices for performance study, must draw up a declaration of conformity in accordance with regulation 151, and affix the CE marking of conformity in accordance with regulation 152.

(8) Manufacturers must comply with the obligations relating to the UDI system referred to in regulation 157 and with the registration obligations referred to in regulations 158 and 160.

(9) Manufacturers must keep the technical documentation, the declaration of conformity and, if applicable, a copy of the relevant certificate (including any amendments and supplements) available for the Secretary of State for a period of at least 10 years after the last device covered by the declaration of conformity has been placed on the market.

(10) 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.

(11) A manufacturer with place of business outside the United Kingdom must ensure that the person placing the product on the market has the necessary documentation permanently available.

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

(b) ensuring that for devices (other than devices for performance study) 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.

(13) The quality management system required by paragraph (12) must—

(a) cover all parts and elements of a 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 17;

(vi) performance evaluation, in accordance with regulation 167 and Schedule 27, including PMPF;

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

(viii) verification of the UDI assignments made in accordance with regulation 157 to all relevant devices and ensuring consistency and validity of information provided in accordance with regulation 158;

(ix) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with regulation 185;

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

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

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

(14) Manufacturers of devices must implement and keep up to date the post-market surveillance system in accordance with regulation 185.

(15) Manufacturers must ensure that—

(a) the device is accompanied by the information set out in paragraph 20 of Schedule 17 in English;

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

(16) Manufacturers that 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.

(17) Manufacturers must have a system for recording and reporting of incidents and field safety corrective actions as described in regulations 190 and 191.

(18) Manufacturers must, when they are required to do so by the Secretary of State—

(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 needed 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.

(19) A manufacturer who fails to cooperate with a requirement imposed by paragraph (18) or who provides documentation which is incomplete or incorrect, 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.

(20) Subject to the Data Protection Act 2018(**3**) 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 (18) 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.

(21) The Secretary of State need not comply with the requirement in paragraph (20) where the disclosure of the information and documentation is to be dealt with in legal proceedings.

(22) 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 documentation submitted in accordance with regulation 160.

(23) Manufacturers 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 device.

UK responsible person

146. 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.

(**3**) 2018 c. 12.

General obligations of importers

147.—(1) Importers must place on the market only devices 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 157.

(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 must—

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

(b) inform the manufacturer and, if applicable, the manufacturer's authorised representative and UK responsible person;

(4) Where the importer considers or has reason to believe that the 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;

(d) the address at which they can be contacted.

(6) Importers must ensure that any additional label does not obscure any 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 its compliance with the general safety and performance requirements set out in Schedule 17;

(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 and distributors 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) immediately inform the manufacturer and, if applicable, the manufacturer's authorised representative and UK responsible person;

(b) cooperate with the manufacturer, the manufacturer's authorised representative and UK responsible person and the Secretary of State to ensure that the necessary corrective action to bring that 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 a certificate, and must give details, in particular, of the non-compliance giving rise to the risk and of any corrective action taken.

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

(13) Importers must keep a copy of the declaration of conformity and any relevant certificate, for the period referred to in regulation 145(9).

(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

148.—(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 that 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 145(15);

(c) for imported devices, the importer has complied with the requirements set out in regulation 147(8);

(d) 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.

(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 it 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, UK responsible person and the importer;

(b) cooperate with the manufacturer, with the Secretary of State, where applicable, with the manufacturer's authorised representative, the UK responsible person and with 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

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

(2) Subject to paragraph (3), the requisite expertise in paragraph 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 in vitro diagnostic medical devices.

(3) Where a manufacturer manufacturers 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(**4**) (as it applies 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 145(14);

(d) the reporting obligations referred to in regulations 190 to 193 are fulfilled;

(e) in the case of investigational devices, the statement referred to in paragraph 3(a) of Chapter II of Schedule 28 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

150.—(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 a 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—

(**4**) OJ L 124, 20.5.2003, p. 36.

(a) provision of information supplied by the manufacturer, in accordance with paragraph 20 of Schedule 17, 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 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 paragraphs (4) and (5).

Declaration of conformity

151.—(1) The declaration of conformity must state that the requirements specified in this Part, or the equivalent provisions of Regulation (EU) 2017/746, have been fulfilled in relation to the device that is covered and the manufacturer must continuously update the declaration of conformity.

(2) The declaration of conformity must, at least, contain the information set out in Schedule 20 and must 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

152.—(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, as presented in Schedule 21.

(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 it 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 163 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

153.—(1) The Secretary of State must not create obstacles to devices for performance study being supplied to an investigator for the purpose of a clinical investigation if they meet the requirements of this Part.

(2) The devices to which paragraph (1) relates must not bear a CE marking.

(3) 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 are 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.

Parts and components

154.—(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;

(b) keep supporting evidence available 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

155.—(1) Distributors and importers must cooperate with manufacturers (or 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 145(9)—

(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

156.—(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

157.—(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 22;

(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 22;

(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) respectively;

(d) establishment of an electronic system for Unique Device Identification ('UDI database') in accordance with regulation 159.

(2) Before placing a device, other than a device for performance study, 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 device for performance study, is placed on the market the manufacturer must ensure that the information referred to in Part B of Schedule 22

about the device is correctly submitted and transferred to the UDI database referred to in regulation 92.

(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 190.

(6) The Basic UDI-DI of the device must appear on the declaration of conformity referred to in regulation 151.

(7) As part of the technical documentation referred to in Schedule 18 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 the devices, categories or groups of devices determined by regulations made under paragraph (10).

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

(10) 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 22 in the light of technical progress;

(c) amend Schedule 22 in the light of international developments and technical progress.

(11) In this regulation and regulation 158 "issuing entity" means an organisation designated by the European Commission for the purpose of issuing UDIs pursuant to Regulation 2017/746 of the European Parliament and the Council of 5th April 2017 as it applies in the European Union(**5**).

Registration of devices

158.—(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 157(2), assign a Basic UDI-DI to the device and must provide it to the UDI database together with the other core data elements referred to in Part B of Schedule 22 related to that device.

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

Electronic system for registration of economic operators

159.—(1) The Secretary of State must set up and manage an electronic system to create a registration number for the purpose of identifying the manufacturer and, where applicable, the importer, authorised representative, the UK responsible person and distributor.

(2) The details of the information to be provided to the electronic system are set out in paragraph 1 of Part A of Schedule 22.

(**5**) OJ no. L 117, 5.5.2017, p.1.

Registration of economic operators

160.—(1) No person may place a 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 on the market—

(a) a manufacturer must register with the electronic system referred to in regulation 159 and provide the information set out in paragraph 1 of Part A of Schedule 22;

(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 159.

(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 22.

(4) Within one week of a change occurring in the information referred to in paragraph (2), the person must update the information in the electronic system referred to in regulation 159.

(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 performance

161.—(1) For Class C and D devices, other than devices for performance studies, a manufacturer must draw up a summary of safety and performance.

(2) The summary of safety and 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 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 performance evaluation as referred to in Schedule 27, and relevant information on PMPF;

(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 performance.

Classification of devices

162. Devices to which this Part applies must be divided into Classes A, B, C and D, according to the classification rules in Schedule 23.

Conformity assessment procedures

163.—(1) 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 24 to 26.

(2) Class D devices, other than devices for performance study, must be subject to—

(a) a conformity assessment as specified in Parts 1 and 3 of Schedule 24; or

(b) a conformity assessment as specified in Schedule 25 coupled with a conformity assessment as specified in Schedule 26.

(3) In addition to the procedures in paragraph (2) for Class D devices for self-testing and near patient testing, the manufacturer must follow the procedure for technical documentation assessment set out in paragraph 3 of Schedule 24.

(4) Class C devices, other than devices for performance study, must be subject to conformity assessment procedure—

(a) as specified in Parts 1 and 3 of Schedule 24, including an assessment of the technical documentation of at least one representative device per generic device group; or

(b) as specified in Schedule 25 coupled with a conformity assessment as specified in Schedule 26 (except for paragraph 4).

(5) In addition to the procedures in paragraph (4) for Class C devices for self-testing and near patient testing, the manufacturer must follow the procedure for technical documentation assessment set out in paragraph 3 of Schedule 24.

(6) Class B devices, other than devices for performance study, must be subject to a conformity assessment as specified in Parts 1 and 3 of Schedule 24, including an assessment of the technical documentation for at least one representative device per category of devices.

(7) In addition to the procedures in paragraph (6) for Class B devices for self-testing and near patient testing, the manufacturer must follow the procedure for technical documentation assessment set out in paragraph 3 of Schedule 24.

(8) Subject to paragraph (9), Class A devices, other than devices for performance study, must declare the conformity of their products by issuing a declaration of conformity referred to in regulation 151, after drawing up the technical documentation set out in Schedules 18 and 19.

(9) If Class A devices are placed on the market in a sterile condition, the manufacturer must apply the procedures set out in Schedule 24 or in Schedule 26.

(10) Devices for performance study must be subject to the requirements of regulations 168 to 185.

Involvement of notified bodies

164.—(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 conformity assessment and CE marking etc.

165.—(1) The requirements of regulation 164 do not apply where—

(a) 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;

(b) 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 158 or 160, 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

166.—(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, performance evaluation and performance studies

Performance evaluation and clinical evidence

167.—(1) Confirmation of conformity with relevant general safety and performance requirements set out in Schedule 17, in particular those concerning the performance characteristics referred to in Part 1 and paragraph 9 of Schedule 17, under the normal conditions of the intended use of the device, and the evaluation of the interference and cross-reactions and of the acceptability of the benefit-risk ratio referred to in paragraphs 1 and 8 of Schedule 17, must be based on scientific validity, analytical and clinical performance data providing sufficient clinical evidence, including where applicable relevant data as referred to in Schedule 19.

(2) The manufacturer must specify and justify the level of the 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 performance evaluation in accordance with this regulation and with Part A of Schedule 27.

(4) The clinical evidence must support the intended purpose of the device as stated by the manufacturer and be based on a continuous process of performance evaluation, following a performance evaluation plan.

(5) A performance evaluation must follow a defined and methodologically sound procedure for the demonstration of the following, in accordance with this regulation and with Part A of Schedule 27—

(a) scientific validity;

(b) analytical performance;

(c) clinical performance.

(6) The data and conclusions drawn from the assessment of the elements in paragraph (5) must constitute the clinical evidence for the device and the clinical evidence must be such as to scientifically demonstrate, by reference to the state of the art in medicine, that the intended clinical benefit will be achieved and that the device is safe.

(7) The clinical evidence derived from the performance evaluation must provide scientifically valid assurance, that the relevant general safety and performance requirements set out in Schedule 17, are fulfilled, under normal conditions of use.

(8) Clinical performance studies in accordance with paragraph 2 of Part A of Schedule 27 must be carried out unless it is duly justified to rely on other sources of clinical performance data.

(9) The scientific validity data, the analytical performance data and the clinical performance data, their assessment and the clinical evidence derived from that data, shall be documented in the performance evaluation report referred to in paragraph 1(21) to (22) of Part A of Schedule 27.

(10) The performance evaluation report must be part of the technical documentation, referred to in Schedule 18, relating to the device concerned.

(11) The performance evaluation and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's PMPF plan in accordance with Part B of Schedule 27 and the post-market surveillance plan referred to in regulation 187.

(12) The performance evaluation report for Class C and D devices must be updated when necessary, but at least annually, with the data referred to in the paragraph (11) and the summary of safety and performance referred to in regulation 161 must be updated as soon as possible, where necessary.

General requirements regarding performance studies

168.—(1) The manufacturer must ensure that a device for performance study complies with the general safety and performance requirements set out in Schedule 17 apart from the aspects covered by the performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.

(2) Where appropriate, performance studies must be performed in circumstances similar to the normal conditions of use of the device.

(3) Performance studies must be designed and conducted in such a way that the rights, safety, dignity and well-being of the subjects participating in such performance studies are protected and prevail over all other interests and the data generated are scientifically valid, reliable and robust.

Additional requirements for certain performance studies

169.—(1) Any performance study—

(a) in which surgically invasive sample-taking is done only for the purpose of the performance study;

(b) that is an interventional clinical performance study; or

(c) where the conduct of the study involves additional invasive procedures or other risks for the subjects of the studies,

must, in addition to meeting the requirements set out in regulation 168 and Schedule 27, be designed, authorised, conducted, recorded and reported in accordance with this regulation, regulations 170 to 185 and Schedule 28.

(2) Performance studies involving companion diagnostics must be subject to the same requirements as the performance studies listed in paragraph (1).

(3) Paragraph (2) does not apply to performance studies involving companion diagnostics using only left-over samples but such studies must be notified to the Secretary of State.

(4) Performance studies must be subject to scientific and ethical review performed by an ethics committee whose procedures for review are compatible with the procedures for the assessment of an application for authorisation of a performance study set out in this Part.

(5) Where the sponsor of a performance study is not established in the United Kingdom—

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

(b) such legal representative shall 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; and

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

(6) A performance study as referred to in paragraph (1) may be conducted only where all of the following conditions are met—

(a) the performance study is the subject of an authorisation by the Secretary of State in accordance with this Part, unless otherwise stated;

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

(c) the sponsor or its legal representative or a contact person pursuant to paragraph (5) is established in the United Kingdom;

(d) vulnerable populations and subjects are appropriately protected in accordance with regulations 170 to 174;

(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) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has given informed consent, in accordance with regulation 170;

(g) the subject or, where the subject is not able to give informed consent, his or her 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 him or her in accordance with the Data Protection Act 2018 are safeguarded;

(i) the performance study 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 performance study plan and constantly monitored;

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

(k) no undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on his or her legally designated representatives, to participate in the performance study;

(l) where appropriate, biological safety testing reflecting the latest scientific knowledge or any other test deemed necessary in the light of the device's intended purpose has been conducted;

(m) in the case of clinical performance studies, the analytical performance has been demonstrated, taking into consideration the state of the art;

(n) in the case of interventional clinical performance studies, the analytical performance and scientific validity has been demonstrated, taking into consideration the state of the art and where, for companion diagnostics, the scientific validity is not established, the scientific rationale for the use of the biomarker shall be provided;

(o) the technical safety of the device with regard to its use has been proven, taking into consideration the state of the art as well as provisions in the field of occupational safety and accident prevention;

(p) the requirements of Schedule 28 are fulfilled.

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

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

(9) 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 or laboratory medicine and other personnel involved in conducting a

performance study must be suitably qualified, by education, training or experience in the relevant medical field and in clinical research methodology, to perform their tasks.

(10) Where appropriate, the facilities where the performance study involving subjects is to be conducted must be suitable for the performance study and shall be similar to the facilities where the device is intended to be used.

Informed consent

170.—(1) Informed consent—

(a) must be written, dated and signed by the person performing the interview referred to in paragraph 170(2)(c), and by the subject or, where the subject is not able to give informed consent, his or her legally designated representative after having been duly informed in accordance with paragraph 170(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 must be provided to the subject or 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 their decision to participate in the performance study.

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

(a) enable the subject or his or her legally designated representative to understand—

(i) the nature, objectives, benefits, implications, risks and inconveniences of the performance study;

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

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

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

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

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

(d) include information about the applicable damage compensation system referred to in regulation 175.

(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, his or her 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;

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

(5) The subject must be informed that a performance study report and a summary presented in terms understandable to the intended user will be made available irrespective of the outcome of the performance study, 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.

Performance studies on incapacitated subjects

171.—(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 performance study may be conducted only where, in addition to the conditions set out in regulation 169(6), all of the following conditions are met—

(a) unless regulation 174 applies, the informed consent of their legally designated representative has been obtained;

(b) unless regulation 174 applies, the incapacitated subjects have received the information referred to in regulation 171 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 170(2) to refuse participation in, or to withdraw from, the performance study 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 performance study;

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

(f) the performance study relates directly to a medical condition from which the subject suffers;

(g) there are scientific grounds for expecting that participation in the performance study will produce—

(i) a direct benefit to the incapacitated subject outweighing the risks and burdens involved; or

(ii) some benefit for the population represented by the incapacitated subject concerned when the performance study will pose only minimal risk to, and will impose minimal burden on, the incapacitated subject concerned in comparison with the standard treatment of the incapacitated subject's condition.

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

Performance studies on minors

172. A performance study on minors may be conducted only where, in addition to the conditions set out in regulation 169(6) all of the following conditions are met—

(a) the informed consent of their legally designated representative has been obtained;

(b) the minors have received the information referred to in regulation 170(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 170(2) to refuse participation in, or to withdraw from, the performance study 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 performance study;

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

(f) the performance study 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 performance study will produce—

(i) a direct benefit to the minor subject outweighing the risks and burdens involved; or

(ii) some benefit for the population represented by the minor concerned when the performance study will pose only minimal risk to, and will impose minimal burden on, the minor concerned in comparison with the standard treatment of the minor's condition;

(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 performance study, 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.

Performance studies on pregnant or breastfeeding women

173. A performance study on a pregnant or breastfeeding woman may be conducted only where, in addition to the conditions set out in regulation 169(6), all of the following conditions are met—

(a) the performance study 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) if such a performance study has no direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, it can be conducted only if—

(i) a performance study of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding;

(ii) the performance study contributes to the attainment of results capable of benefitting pregnant or breastfeeding women or other women in relation to reproduction or other embryos, foetuses or children; and

(iii) the performance study poses a minimal risk to, and imposes a minimal burden on, the pregnant or breastfeeding woman concerned, her embryo, foetus or child after birth;

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

(d) no incentives or financial inducements are given to subjects, except for compensation for expenses and loss of earnings directly related to the participation in the performance study.

Performance studies in emergency situations

174.—(1) Informed consent to participate in a performance study may be obtained, and information on the performance studies may be given, after the decision to include the subject in the performance study, provided that that decision is taken at the time of the first intervention on the subject, in accordance with the clinical performance study plan for that performance study 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 performance study;

(b) there are scientific grounds to expect that participation of the subject in the performance study 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 performance study previously expressed by the subject;

(e) the performance study 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 performance study is of such a nature that it may be conducted exclusively in emergency situations;

(f) the performance study 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 170 must be sought to continue the participation of the subject in the performance study, and information on the performance study 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 the subject's legally designated representative without undue delay and the information referred to in regulation 170(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 170(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 performance study 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 performance study.

Damage compensation

175. 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 performance study.

Application for performance studies

176.—(1) The sponsor of a performance study must submit an application to the Secretary of State accompanied by the documentation referred to in paragraphs 2 and 3 of Schedule 27 and in Schedule 28.

(2) Within 10 days of receiving the application, the Secretary of State must notify the sponsor as to whether the performance study falls within the scope of this Part and as to whether the application dossier is complete in accordance with Part 1 of Schedule 28.

(3) Within one week of any change occurring in relation to the documentation referred to in Part 1 of Schedule 28, the sponsor must—

(a) update 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 performance study 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, 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 performance study is considered as falling within the scope of this Part or, as the case maybe, whether 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 the clinical investigation in the following circumstances—

(a) in the case of performance studies in which surgically invasive sample-taking is done only for the purpose of the performance study, provided that a negative opinion has not been issued by an ethics committee in the United Kingdom in respect of the performance study, immediately after the validation date of the application pursuant to paragraph (8);

(b) in the case of performance studies, carried out pursuant to regulation 169(b) or (c) or performance studies other than those referred to in sub-paragraph (a), provided a negative opinion in respect of the clinical investigation has not been issued by an ethics committee in the United Kingdom, as soon as the Secretary of State has notified the sponsor of the Secretary of State's authorisation.

(10) For the purposes of paragraph (9)(b) 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

177.—(1) The Secretary of State must ensure that the persons validating and assessing the performance study 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 performance study;

(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 performance study 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 CS or designated standards, examine in particular—

(i) the demonstration of compliance of the devices for performance study with the applicable general safety and performance requirements, apart from the aspects covered by the performance study, 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, the evaluation of the analytical performance, clinical performance and scientific validity, taking into consideration the state of the art;

(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 standards;

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

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

(v) whether the requirements of Schedule 28 are met.

(4) The Secretary of State must refuse the authorisation of the performance study if—

(a) the application dossier submitted remains incomplete;

(b) the device or the submitted documents, especially the performance study plan and the investigator's brochure, do not correspond to the state of scientific knowledge, and the performance study, 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 168 are not met; or

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

Appeal rights

178.—(1) Where the sponsor is dissatisfied with a decision taken by the Secretary of State under regulation 176(6) or regulation 177(4), the sponsor or the sponsor's legally designated representative in the United Kingdom may require the Secretary of State to seek advice from such a person as the Institute determines on—

(a) whether the performance study 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 performance study

179.—(1) The sponsor and the investigator must ensure that the performance study is conducted in accordance with the approved performance study plan.

(2) The sponsor—

(a) must ensure adequate monitoring of the conduct of the performance study in order to—

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

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

(iii) that the conduct of the performance study 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 performance study including the following—

(i) the objective and methodology of the performance study;

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

(3) All performance study 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, performance study sites to check that performance studies 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 study.

Performance studies regarding devices bearing the CE marking -intended purpose

180.—(1) Where—

(a) a performance study 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 152(1) ('PMPF study');

(b) the performance study 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 the documentation referred to in paragraph 2 of Part A of Schedule 27 and in Schedule 28.

(3) The following provisions apply to PMPF studies—

(a) sub-paragraphs (b) to (l) and (p) of paragraph 169;

(b) regulations 182, 183, 184 and 185(6) and the relevant provisions of Schedules 27 and 28.

Performance studies regarding devices bearing the CE marking outside intended purpose

181. Where a performance study 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 152(1), regulations 168 to 185 apply.

Substantial modifications to performance studies

182.—(1) If a sponsor intends to introduce modifications to a performance study 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 data generated by the study, 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 Schedule 28 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 performance study in accordance with the procedure laid down in regulation 177.

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

(a) the Secretary of State has notified the sponsor of its refusal based on the grounds referred to in regulation 177(4) or on considerations of public health, of subject and user safety or health, or of public policy; or

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

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

Corrective measures to be taken by the Secretary of State on performance studies

183.—(1) Where the Secretary of State has grounds for considering that the requirements of this Part are not met, the Secretary of State may take any of the following actions—

(a) revoke the authorisation for the performance study;

(b) suspend or terminate the performance study;

(c) require the sponsor to modify any aspect of the performance study.

(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 for their opinion which must be delivered within 7 days.

Information from the sponsor at the end of a performance study or in the event of a temporary halt or early termination

184.—(1) Subject to paragraph (2) if the sponsor has temporarily halted a performance study or has terminated a performance study early, the sponsor must inform the Secretary of State of that halt or termination within 15 days of the date of the temporary halt or termination.

(2) Where the sponsor has temporarily halted the performance study 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 performance study is deemed to coincide with the last visit of the last subject unless another point in time for such an end is set out in the performance study plan.

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

(5) Irrespective of the outcome of the performance study but subject to paragraph (7), within one year of the end of the performance study or within 3 months of the early termination or temporary halt, the sponsor must submit to the Secretary of State a performance study report as referred to in paragraph 1(10) to (12) of Part A of Schedule 27.

(6) The performance study 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 the summary.

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

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

(b) specify in the clinical performance study plan referred to in sub-paragraphs (6) to (8) of Part A of Schedule 27 when the results of the performance study 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 may—

(a) issue guidelines regarding the content and structure of the summary of the performance study report;

(b) 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 performance studies.

(9) The summary and performance study report referred to in paragraph (6) must—

(a) in circumstances other than those provided for in sub-paragraphs (b) and (c), become publicly accessible at least when it is registered in accordance with regulation 158 and before it is placed on the market;

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

(c) if the device is not registered in accordance with regulation 158, become publicly accessible within one year of the summary and the report having been submitted pursuant to paragraph (6).

Recording and reporting of adverse events that occur during performance studies

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

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

(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 device, the comparator or the study 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 points (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 shall 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 performance study is performed under the same clinical performance study plan as the one applying to a performance study covered by this Part.

(6) Subject to paragraph (7), this regulation does not apply to PMPF studies referred to in regulation 180 but the provisions on vigilance provided for in regulations 190 to 193 apply instead of this regulation.

(7) This regulation must apply where a causal relationship between the serious adverse event and the preceding performance study has been established.

Post-market surveillance, vigilance and market surveillance

Post market surveillance system of the manufacturer

186.—(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 145(13).

(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; and

(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 17;

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

(iii) to update the performance evaluation;

(iv) to update the summary of safety and performance referred to in regulation 161;

(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; and

(viii) detect and report trends in accordance with 191;

(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, it must be reported in accordance with regulation 190.

Post-market surveillance plan

187. The post-market surveillance system referred to in regulation 186 must be based on a post-market surveillance plan which satisfies the requirements set out in paragraph 1 of Schedule 19 and must be part of the technical documentation specified in Schedule 18.

Post-market surveillance report

188.—(1) Manufacturers of Class A and B 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 187 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 notified body and the Secretary of State upon request.

Periodic safety update report

189.—(1) Manufacturers of Class C and Class D 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 187, 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 PMPF; and

(c) the volume of sales of the device and an estimate 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 C and D devices must—

(a) update the PSUR at least annually;

(b) ensure that the PSUR is part of the technical documentation as specified in Schedules 18 and 19.

(4) Manufacturers of Class D devices must—

(a) submit PSUR to the notified body involved in the conformity assessment of such devices in accordance with regulation 163;

(b) make the PSUR available to the Secretary of State.

(5) For Class C devices, manufacturers must make PSURs available to the notified body involved in the conformity assessment and, upon request, to the Secretary of State.

Reporting of serious incidents and field safety corrective actions

190.—(1) Manufacturers of devices, made available on the market, other than devices for performance study must report to the Secretary of State the following—

(a) any serious incident involving devices made available on the market, except expected erroneous results which are clearly documented and quantified in the product information, in the technical documentation and are subject to trend reporting pursuant to regulation 191;

(b) any field safety corrective action in respect of devices made available on the market, including any field safety corrective action undertaken in a country outside the United Kingdom 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 country outside the United Kingdom.

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

(3) Manufacturers must report any serious incident as referred to in paragraph (1)(a) immediately after they have established a 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) Notwithstanding paragraph (3), in the event of a serious public health threat the report referred to in paragraph (1) shall be provided immediately, and not later than 2 days after the manufacturer becomes aware of that threat.

(5) Notwithstanding paragraph (3), in the event of death or an unanticipated serious deterioration in a person's state of health the report shall 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 shall 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 shall, 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 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 the incident is a serious incident, it shall provide a report in accordance with paragraphs (1) to (5) on that serious incident to the Secretary of State and shall take the appropriate follow-up action in accordance with Article 192.

(13) Where—

(a) the manufacturer of the device concerned considers that the incident is not a serious incident or is to be treated as an increase in expected erroneous results, which will be covered by trend reporting in accordance with to regulation 191, the manufacturer must provide an explanatory statement; and

(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); and

(ii) to ensure that appropriate follow-up action is taken in accordance with regulation 192.

Trend reporting

191.—(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 that could have a significant impact on the benefit-risk analysis referred to in paragraphs 1 and 5 of Schedule 17 and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons or of any significant increase in expected erroneous results established in comparison to the stated performance of the device as referred to in paragraph 9(1) of Schedule 17 and specified in the technical documentation and product information.

(2) 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 events or change in performance, as well as the observation period, in the post-market surveillance plan referred to in regulation 187.

(3) 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

192.—(1) Following the reporting of a serious incident pursuant to regulation 190(1), the manufacturer must—

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

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

(2) The manufacturer must—

(a) cooperate with the Secretary of State and where relevant with the notified body concerned 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 190 is evaluated, if possible together with the manufacturer, and, where relevant, the notified body concerned.

(4) In the context 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 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 17.

(5) Upon request by the Secretary of State, manufacturers must provide for 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, may intervene in a manufacturer's investigation or initiate an independent investigation.

(7) The manufacturer must provide a final report to the Secretary of State setting out the manufacturer's findings from the investigation which must set out conclusions and, where relevant, indicate corrective actions to be taken.

(8) The 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.

(9) 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) must clearly indicate all the actions to be taken by users;

(d) be accessible to the public.

Analysis of vigilance data

193.—(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 shall then take the necessary corrective actions.

Electronic system on vigilance and post-market surveillance

194.—(1) The Secretary of State must set up and mange an electronic system to collate and process the following information

(a) 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 issued 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 purposes of granting access (at an appropriate level) to the electronic system in paragraph (1);

(b) must only make 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

195.—(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) in doing so, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.

(2) The Secretary of State must—

(a) draw up annual surveillance activity plans;

(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 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 the authorities' 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, as well as 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 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 requirements 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 the market surveillance activities; and

(b) make a summary of the results of that review available to the public.

(9) Where appropriate, the Secretary of State must cooperate with other 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

196. 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 of the device concerned 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

197.—(1) Where, having performed an evaluation pursuant to regulation 196, 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—

(a) must without delay require the manufacturer of the devices concerned and all other relevant economic operators 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) may, 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 to specific requirements, withdraw the device from the market, or to recall it within a reasonable period that is clearly defined and communicated to the relevant economic operator.

(2) The economic operators 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 may take action in accordance with regulation 63 or Part II of the Consumer Protection Act 1987.

Other non-compliance

198.—(1) Where, having performed an evaluation pursuant to regulation 196, 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 may take action in accordance with regulation 62 or, following such action, Part II the Consumer Protection Act 1987.

Regulations

199.—(1) Regulations under this Part may—

(a) make different provisions 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 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.”.