Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)

CHAPTER I

SCOPE AND DEFINITIONS

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

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

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

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

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

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

(3) ‘custom-made device’ means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;

(4) 'active device' means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices.

Software shall also be deemed to be an active device;

(5) 'implantable device' means any device, including those that are partially or wholly absorbed, which is intended:

— to be totally introduced into the human body, or

— to replace an epithelial surface or the surface of the eye,

by clinical intervention and which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device;

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

(7) '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;

(8) 'single-use device' means a device that is intended to be used on one individual during a single procedure;

(9) 'falsified device' means any device with a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights;

(10) 'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose;

(11) 'system' means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose;

(12) 'intended purpose' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation;

(13) '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;

(14) '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;

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

(16) 'non-viable' means having no potential for metabolism or multiplication;

(17) 'derivative' means a 'non-cellular substance' extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case does not contain any cells or tissues;

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

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall also be deemed to be nanomaterials;

(19) 'particle', for the purposes of the definition of nanomaterial in point (18), means a minute piece of matter with defined physical boundaries;

(20) 'agglomerate', for the purposes of the definition of nanomaterial in point (18), means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

(21) 'aggregate', for the purposes of the definition of nanomaterial in point (18), means a particle comprising of strongly bound or fused particles;

(22) 'performance' means the ability of a device to achieve its intended purpose as stated by the manufacturer;

(23) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;

(24) '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;

(25) '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:

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

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

(c) be used together without conflict/interference or adverse reaction.

(26) 'interoperability' is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to:

(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, and/or

(b) communicate with each other, and/or

(c) work together as intended.

(27) ‘making available on the market’ means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(28) ‘placing on the market’ means the first making available of a device, other than an investigational device, on the Union market;

(29) ‘putting into service’ means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

(30) ‘manufacturer’ means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;

(31) ‘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 Regulation, combined with the assignment of a new lifetime to the refurbished device;

(32) ‘authorised representative’ means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

(33) ‘importer’ means any natural or legal person established within the Union that places a device from a third country on the Union market;

(34) ‘distributor’ means any natural or legal 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;

(35) ‘economic operator’ means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3);

(36) ‘health institution’ means an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health;

(37) ‘user’ means any healthcare professional or lay person who uses a device;

(38) ‘lay person’ means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

(39) ‘reprocessing’ means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device;

(40) ‘conformity assessment’ means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;

(41) ‘conformity assessment body’ means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;

(42) ‘notified body’ means a conformity assessment body designated in accordance with this Regulation;

(43) '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 Regulation and other applicable Union harmonisation legislation providing for its affixing;

(44) 'clinical evaluation' means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer;

(45) 'clinical investigation' means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device;

(46) 'investigational device' means a device that is assessed in a clinical investigation;

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

(48) 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

— clinical investigation(s) of the device concerned,

— clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,

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

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

(49) '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 clinical investigation;

(50) 'subject' means an individual who participates in a clinical investigation;

(51) 'clinical evidence' means clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer;

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

(53) 'clinical benefit' means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health;

(54) 'investigator' means an individual responsible for the conduct of a clinical investigation at a clinical investigation site;

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

(56) ‘ethics committee’ means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;

(57) ‘adverse event’ means any untoward medical occurrence, 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 clinical investigation, whether or not related to the investigational device;

(58) ‘serious adverse event’ means any adverse event that led to any of the following:

(a) death,

(b) serious deterioration in the health of the subject, that resulted in any of the following:

(i) life-threatening illness or injury,

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

(iii) hospitalisation or prolongation of patient hospitalisation,

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

(v) chronic disease,

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

(59) ‘device deficiency’ means any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer;

(60) ‘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;

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

(62) ‘recall’ means any measure aimed at achieving the return of a device that has already been made available to the end user;

(63) ‘withdrawal’ means any measure aimed at preventing a device in the supply chain from being further made available on the market;

(64) ‘incident’ means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect;

(65) ‘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) a serious public health threat;

(66) ‘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;

(67) ‘corrective action’ means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation;

(68) ‘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;

(69) ‘field safety notice’ means a communication sent by a manufacturer to users or customers in relation to a field safety corrective action;

(70) ‘harmonised standard’ means a European standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012;

(71) ‘common specifications’ (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.

Status:
Point in time view as at 05/04/2017. This version of this provision has been superseded.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2017/745 of the European Parliament and of the Council, Article 2.