goods and legal certainty for manufacturers, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial[33], with the necessary flexibility to adapt this definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of medical devices, the manufacturers should take special care when using nanoparticles that can be released to the human body and those devices should be subject to the most severe conformity assessment procedure.

(14) Aspects addressed by Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC[34] and aspects addressed by Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC[35] are an integral part of the general safety and performance requirements for medical devices. Consequently, this Regulation should be considered a *lex specialis* in relation to those Directives.

(15) This Regulation should include requirements regarding the design and manufacture of medical devices emitting ionizing radiation without affecting the application of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation[36] nor of Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure and repealing Directive 84/466/Euratom[37] which pursue other objectives.

(16) It should be made clear that the requirements of this Regulation also apply to the countries that have entered into international agreements with the Union which confer on that country the same status as a Member State for the purpose of application of this Regulation, as it is currently the case with the Agreement on the European Economic Area[38], the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment[39] and the Agreement of 12 September 1963 establishing an association between the European Economic Community and Turkey[40].

(17) It should be made clear that medical devices offered to persons in the Union by means of information society services within the meaning of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations[41] as well as devices used in the context of a commercial activity to provide a diagnostic or

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33 OJ L 275, 20.10.2011, p. 38.
34 OJ L 390, 31.12.2004, p. 24
35 OJ L 157, 9.6.2006, p. 24.
36 OJ L 159, 29.6.1996, p. 1.
37 OJ L 180, 9.7.1997, p. 22.
38 OJ L 1, 3.1.1994, p. 3.
39 OJ L 114, 30.4.2002, p. 369.
40 OJ 217, 29.12.1964, p. 3687.
41 OJ L 204, 21.7.1998, p. 37, as amended by Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998, OJ L 217, 5.8.1998, p. 18.

therapeutic service to persons within the Union must comply with the requirements of this Regulation at the latest when the product is placed on the market or the service is provided in the Union.

(18) It is appropriate to adapt the general safety and performance requirements to technical and scientific progress, for example for software that is specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device.

(19) To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No [.../...] on European standardisation[42] should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as quality and risk management.

(20) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices[43] allows the Commission to adopt common technical specifications for specific categories of *in vitro* diagnostic medical devices. In areas where no harmonised standards exist or where they are not sufficient, the Commission should be empowered to lay down technical specifications which provide a means to comply with general safety and performance requirements and requirements for clinical evaluation and/or post-market clinical follow-up.

(21) The definitions in the field of medical devices, for example regarding economic operators, clinical investigations and vigilance, should be aligned with well-established practice at Union and international level in order to enhance legal certainty.

(22) The rules applicable to medical devices should be aligned, where appropriate, with the New Legislative Framework for the Marketing of Products, which consists of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93[44] and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC[45].

(23) The rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to medical devices and their accessories covered by this Regulation which does not prevent Member States from choosing the competent authorities to carry out those tasks.

(24) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors as laid down in the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the different parts of this Regulation, to enhance understanding of the

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42 OJ L [...], [...], p. [...].
43 OJ L 331, 7.12.1998, p. 1.
44 OJ L 218, 13.8.2008, p. 30.
45 OJ L 218, 13.8.2008, p. 82.

legal requirements and thus to improve regulatory compliance by the relevant operators.

(25) Several of the obligations on manufacturers, such as clinical evaluation or vigilance reporting, that were set out only in the annexes of Directives 90/385/EEC and 93/42/EEC should be incorporated into the enacting provisions of this Regulation to enhance legal certainty.

(26) To ensure that medical devices manufactured in series production continue to be in conformity with the requirements of this Regulation and that experience from the use of their medical devices is taken into account for the production process, all manufacturers should have a quality management system and a post-market surveillance plan in place which should be proportionate to the risk class and the type of the medical device.

(27) It should be ensured that supervision and control of the manufacture of medical devices is carried out within the manufacturer's organisation by a person who fulfils minimum conditions of qualification.

(28) For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the medical devices produced by those manufacturers and in serving as their contact person established in the Union. The tasks of an authorised representative should be defined in a written mandate with the manufacturer which for example may allow the authorised representative to lodge an application for a conformity assessment procedure, to report events under the vigilance system or to register devices placed on the Union market. The mandate should empower the authorised representative to duly fulfil certain defined tasks. Considering the role of authorised representatives, the minimum requirements to be met by them should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's qualified person but, with a view to the authorised representative's tasks, could also be satisfied by a person with qualification in law.

(29) To ensure legal certainty in respect of the obligations incumbent on economic operators, it is necessary to clarify when a distributor, importer or other person is to be considered the manufacturer of a medical device.

(30) Parallel trade in products already placed on the market is a lawful form of trade within the internal market on the basis of Article 34 TFEU subject to the limitations set by the protection of health and safety and by the protection of intellectual property rights provided by Article 36 TFEU. Application of this principle is, however, subject to different interpretations in the Member States. The conditions, in particular the requirements for relabelling and repackaging, should therefore be specified in this Regulation, taking into account the case-law of the European Court of Justice[46] in other relevant sectors and existing good practices in the field of medical devices.

(31) The findings of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), established by Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field

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46 Judgment of the Court of 28 July 2011 in joined cases C-400/09 and C-207/10.

of consumer safety, public health and the environment and repealing Decision 2004/210/EC[47], in its scientific opinion of 15 April 2010 on the safety of reprocessed medical devices marketed for single-use, and of the Commission in its report of 27 August 2010 to the European Parliament and the Council on the issue of reprocessing of medical devices in the European Union, in accordance with Article 12a of Directive 93/42/EEC[48], call for regulation of the reprocessing of single-use devices in order to ensure a high level of protection of health and safety whilst allowing this practice to further develop under clear conditions. By reprocessing a single-use device its intended purpose is modified and the reprocessor should therefore be considered the manufacturer of the reprocessed device.

(32) Patients who are implanted with a device should be given essential information related to the implanted device allowing it to be identified and containing any necessary warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.

(33) Medical devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation.

(34) The traceability of medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchase-policy and stock-management by hospitals.

(35) Transparency and better information are essential to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

(36) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding medical devices on the market and the relevant economic operators, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) set up by

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47 OJ L 241, 10.9.2008, p. 21.
48 COM(2010)443 final.

Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices[49].

(37) Eudamed's electronic systems regarding devices on the market, the relevant economic operators and certificates should enable the public to be adequately informed about devices on the Union market. The electronic system on clinical investigations should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, in this case, to report serious adverse events. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by national competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

(38) In respect of data collated and processed through the electronic systems of Eudamed, Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[50] applies to the processing of personal data carried out in the Member States, under the supervision of the Member States competent authorities, in particular the public independent authorities designated by the Member States. Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data[51] applies to the processing of personal data carried out by the Commission within the framework of this Regulation, under the supervision of the European Data Protection Supervisor. In accordance with Article 2(d) of Regulation (EC) No 45/2001, the Commission should be designated as the controller of Eudamed and its electronic systems.

(39) For high-risk medical devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the clinical evaluation in a document that should be publicly available.

(40) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

(41) The position of notified bodies vis-à-vis manufacturers should be strengthened, including their right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on medical devices to ensure continuous compliance by manufacturers after receipt of the original certification.

(42) For high risk medical devices, authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, on scientifically valid grounds, to scrutinise the preliminary assessment conducted by notified bodies, in particular regarding novel devices, devices for which a novel

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49 OJ L 102, 23.4.2010, p. 45.
50 OJ L 281, 23.11.1995, p. 31.
51 OJ L 8, 12.1.2001, p. 1.

technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk medical device before submitting the application to the notified body.

(43) It is necessary, in particular for the purpose of the conformity assessment procedures, to maintain the division of medical devices into four product classes in line with international practice. The classification rules, which are based on the vulnerability of the human body taking into account the potential risks associated with the technical design and manufacture of the devices, need to be adapted to technical progress and experience gained from vigilance and market surveillance. To maintain the same level of safety as provided by Directive 90/385/EEC, active implantable medical devices and their accessories should be in the highest risk class.

(44) The conformity assessment procedure for class I devices should be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products. For medical devices in classes IIa, IIb and III, an appropriate level of involvement of a notified body should be compulsory, with medical devices in class III requiring explicit prior approval of their design and manufacture before they can be placed on the market.

(45) The conformity assessment procedures should be simplified and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.

(46) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements should be based on clinical data that, for class III medical devices and implantable medical devices should, as a general rule, be sourced from clinical investigations to be carried out under the responsibility of a sponsor who can be the manufacturer or another legal or natural person taking responsibility for the clinical investigation.

(47) The rules on clinical investigations should be in line with major international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects and the most recent (2008) version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects to ensure that clinical investigations conducted in the Union are accepted elsewhere and that clinical investigations conducted outside the Union in accordance with international guidelines can be accepted under this Regulation.

(48) An electronic system should be set up at Union level to ensure that every clinical investigation is registered in a publicly accessible database. To protect the right to the protection of personal data, recognised by Article 8 of the Charter of Fundamental Rights of the European Union, no personal data of subjects participating in a clinical investigation should be recorded in the electronic system. To ensure synergies with the area of clinical trials on medicinal products, the electronic system on clinical

investigations on medical devices should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use.

(49) Sponsors of clinical investigations to be conducted in more than one Member State should be given the possibility to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety related aspects of the investigational device and of the scientific design of the clinical investigation to be conducted in several Member Stats, such single application should facilitate the coordination between the Member States under the direction of a coordinating Member State. The coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical investigation, including informed consent. Each Member State should retain the ultimate responsibility for deciding whether the clinical investigation may be conducted on its territory.

(50) Sponsors should report certain adverse events occurring during clinical investigations to the Member States concerned, which should have the possibility to terminate or suspend the investigations if considered necessary to ensure a high level of protection of the subjects enrolled in a clinical investigation. Such information should be communicated to the other Member States.

(51) This Regulation should only cover clinical investigations which pursue regulatory purposes laid down in this Regulation.

(52) In order to better protect health and safety regarding devices on the market, the vigilance system for medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

(53) Healthcare professionals and patients should be empowered to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers and share the information with their peers when they confirm that a serious incident has occurred in order to minimise recurrence of those incidents.

(54) The assessment of reported serious incidents and field safety corrective actions should be conducted at national level but coordination should be ensured where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State with the objective of sharing resources and ensuring consistency regarding the corrective action.

(55) The reporting of serious adverse events during clinical investigations and the reporting of serious incidents occurring after a medical device has been placed on the market should be clearly distinguished to avoid double reporting.

(56) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.

(57) The Member States shall levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies.

(58) Whilst this Regulation should not affect the right of Member States to levy fees for activities at national level, Member States should inform the Commission and the other Member States before they adopt the level and structure of the fees to ensure transparency.

(59) An expert committee, the Medical Device Coordination Group (MDCG), composed of persons designated by the Member States based on their role and expertise in the field of medical devices and *in vitro* diagnostic medical devices should be established to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [.../...] on *in vitro* diagnostic medical devices[52], to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation.

(60) Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is fundamental for ensuring a consistently high level of health and safety within the internal market, in particular in the areas of clinical investigations and vigilance. This should also lead to more efficient use of scarce resources at national level.

(61) The Commission should provide scientific, technical and corresponding logistic support to the coordinating national authority and ensure that the regulatory system for medical devices is effectively implemented at Union level based on sound scientific evidence.

(62) The Union should actively participate in international regulatory cooperation in the field of medical devices to facilitate the exchange of safety-related information regarding medical devices and to foster the further development of international regulatory guidelines promoting the adoption of regulations in other jurisdictions with a level of health and safety protection equivalent to that set by this Regulation.

(63) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.

(64) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the products subject to this Regulation that are similar to medical devices but do not necessarily have a medical purpose; adaptation of the definition of nanomaterial to technical progress and to developments at Union and international level; adaptation to technical progress of the general safety and performance requirements, of the elements to be addressed in the technical documentation, of the minimum content of the EU declaration of conformity and of the certificates issued by notified bodies, of the

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52 OJ L [...], [...], p. [...].

minimum requirements to be met by notified bodies, of the classification rules, of the conformity assessment procedures, and of the documentation to be submitted for the approval of clinical investigations; the establishment of the UDI system; the information to be submitted for the registration of medical devices and certain economic operators; the level and structure of fees for the designation and monitoring of notified bodies; the publicly available information in respect of clinical investigations; the adoption of preventive health protection measures at EU level; and the tasks of and criteria for European Union reference laboratories and the level and structure of fees for scientific opinions delivered by them.

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(65) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[53].

(66) The advisory procedure should be used for the adoption of the form and presentation of the data elements of the manufacturers' summary of safety and clinical performance; of the codes defining the notified bodies' scopes of designation; and of the model for certificates of free sale, given that those acts have a procedural character and do not directly impact the health and safety at Union level.

(67) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the extension to the territory of the Union of a national derogation from the applicable conformity assessment procedures in exceptional cases; relating to the Commission's position whether a provisional national measure against a medical device presenting a risk or a provisional national preventive health protection measure is justified or not; and relating to the adoption of a Union measure against a medical device presenting a risk, imperative grounds of urgency so require.

(68) To allow economic operators, notified bodies, Member States and the Commission to adapt to the changes introduced by this Regulation, it is appropriate to provide for a sufficient transitional period for that adaptation and for the organisational arrangements to be taken for its proper application. It is particularly important that by the date of application, a sufficient number of notified bodies are designated in accordance with the new requirements to avoid any shortage of medical devices on the market.

(69) In order to ensure a smooth transition to the registration of medical devices, of relevant economic operators and of certificates, the obligation to submit the relevant information to the electronic systems put in place by this Regulation at Union level should become fully effective only 18 months after the date of application of this

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[53] OJ L 55, 28.2.2011, p. 13.

Regulation. During this transitional period, Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC should remain in force. However, economic operators and notified bodies who register in the relevant electronic systems provided for at Union level should be considered in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directives to avoid multiple registrations.

(70) Directives 90/385/EEC and 93/42/EEC should be repealed to ensure that only one set of rules applies to the placing of medical devices on the market and the related aspects covered by this Regulation.

(71) Since the objective of this Regulation, namely to ensure high standards of quality and safety for medical devices, thus ensuring a high level of protection of health and safety of patients, users and other persons, cannot sufficiently be achieved by the Member States and can, by reason of the scale of the measure, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

HAVE ADOPTED THIS REGULATION:

Chapter I
Scope and definitions

Article 1
Scope

1. This Regulation establishes rules to be complied with by medical devices and accessories to medical devices that are placed on the market or put into service in the Union for human use.

   For the purposes of this Regulation, medical devices and accessories to medical devices shall hereinafter be referred to as 'devices'.

2. This Regulation shall not apply to:

   (a) *in vitro* diagnostic medical devices covered by Regulation (EU) [.../...];

   (b) medicinal products covered by Directive 2001/83/EC and advanced therapy medicinal products covered by Regulation (EC) No 1394/2007. In deciding whether a product falls under Directive 2001/83/EC or Regulation (EC) No 1394/2007 or under this Regulation, particular account shall be taken of the principal mode of action of the product;

   (c) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market or used in accordance with the manufacturer's instructions, such blood products, plasma or cells, except for devices referred to in paragraph 4;

   (d) cosmetic products covered by Regulation (EC) No 1223/2009;

   (e) transplants, tissues or cells of human or animal origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable.

   However, human tissues and cells that are non-viable or are rendered non-viable and that have undergone only non-substantial manipulation, in particular those listed in Annex I of Regulation (EC) No 1394/2007, and products derived from such tissues and cells, shall not be considered devices manufactured utilising tissues or cells of human origin or their derivatives;

   (f) products that contain or consist of biological substances or organisms other than those referred to in points (c) and (e) that are viable, including living micro-organisms, bacteria, fungi or virus;

   (g) food covered by Regulation (EC) No 178/2002.

3. Any device which, when placed on the market or used in accordance with the manufacturer's instructions, incorporates as an integral part an *in vitro* diagnostic

medical device as defined in Article 2 of Regulation (EU) [.../...] [on *in vitro* diagnostic medical devices] shall be governed by this Regulation, unless it is covered by Article 1(3) of that Regulation. The relevant general safety and performance requirements set out in Annex I of that Regulation shall apply as far as the safety and performance of the *in vitro* diagnostic medical device part are concerned.

4. Where a device, when placed on the market or used in accordance with the manufacturer's instructions, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in Article 1(10) of that Directive, with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation.

However, if the action of the medicinal substance is not ancillary to that of the device, the product shall be governed by Directive 2001/83/EC. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.

5. Where a device is intended to administer a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, that device shall be governed by this Regulation, without prejudice to the provisions of Directive 2001/83/EC with regard to the medicinal product.

However, if the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, the product shall be governed by Directive 2001/83/EC. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.

6. This Regulation is a specific Union legislation within the meaning of Article 1(4) of Directive 2004/108/EC and within the meaning of Article 3 of Directive 2006/42/EC.

7. This Regulation shall not affect the application of Council Directive 96/29/Euratom nor of Council Directive 97/43/Euratom.

8. This Regulation shall not affect national laws which require that certain devices may only be supplied on a medical prescription.

9. References to a Member State in this Regulation shall be understood as including any other country with which the Union has concluded an agreement which confers on that country the same status as a Member State for the purpose of application of this Regulation.

Article 2
Definitions

10. For the purposes of this Regulation, the following definitions shall apply:

Definitions related to devices:

(2) '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 specific medical purposes of:

- diagnosis, prevention, monitoring, 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 process or state,
- control or support of conception,
- disinfection or sterilisation of any of the above-mentioned products,

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 implantable or other invasive products, intended to be used for human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.

(3) 'accessory to a medical device' means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable or assist the device(s) to be used in accordance with its/their intended purpose(s);

(4) 'custom-made device' means any device specifically made in accordance with a written prescription of a doctor of medicine, of a dental practitioner or of any other person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient.

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

(5) 'active device' means any device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an

active device and the patient, without any significant change, shall not be considered to be active devices.

Stand alone software shall be considered an active device;

(6) '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 considered an implantable device;

(7) '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;

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

(9) 'single-use device' means a device that is intended to be used on an individual patient during a single procedure.

The single procedure may involve several uses or prolonged use on the same patient;

(10) 'single-use device for critical use' means a single-use device intended to be used for surgically invasive medical procedures;

(11) 'intended purpose' means the use for which the 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;

(12) '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;

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

(14) 'Unique Device Identification' ('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;

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

(16) '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 be considered as nanomaterials.

For the purposes of the definition of nanomaterial, 'particle', 'agglomerate' and 'aggregate' are defined as follows:

- 'particle' means a minute piece of matter with defined physical boundaries;
- 'agglomerate' 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;
- 'aggregate' means a particle comprising of strongly bound or fused particles;

Definitions related to the making available of devices:

(17) '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;

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

(19) '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;

Definitions related to economic operators, users and specific processes:

(20) 'manufacturer' means the 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 his name or trademark.

For the purposes of the definition of manufacturer, fully refurbishing is defined as 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 in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;

(21) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a

manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

(22) 'importer' means any natural or legal person established within the Union who places a device from a third country on the Union market;

(23) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market;

(24) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

(25) 'health institution' means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;

(26) 'user' means any healthcare professional or lay person who uses a device;

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

(28) 'reprocessing' means the 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 restoration of the technical and functional safety of the used device;

Definitions related to conformity assessment:

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

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

(31) 'notified body' means a conformity assessment body designated in accordance with this Regulation;

(32) 'CE marking of conformity' or 'CE marking' means a marking by which the manufacturer indicates that the device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

Definitions related to clinical evaluation and clinical investigations:

(33) 'clinical evaluation' means the assessment and analysis of clinical data pertaining to a device in order to verify the safety and performance of the device when used as intended by the manufacturer;

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

(35) 'investigational device' means any device being assessed for safety and/or performance in a clinical investigation;

(36) 'clinical investigation plan' means the document(s) setting out the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical investigation;

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

- clinical investigation(s) of the device concerned,
- clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated,
- published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;

(38) 'sponsor' means an individual, company, institution or organisation which takes responsibility for the initiation and management of a clinical investigation;

(39) '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;

(40) 'serious adverse event' means any adverse event that led to any of the following:

- death,
- 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 extending the duration of hospitalisation,
  - (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
- foetal distress, foetal death or a congenital abnormality or birth defect;

(41) '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 the information supplied by the manufacturer;

Definitions related to vigilance and market surveillance:

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

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

(44) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, any inadequacy in the information supplied by the manufacturer and any unexpected undesirable side-effect;

(45) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

- death of a patient, user or other person,
- temporary or permanent serious deterioration of the patient's, user's or other person's state of health,
- serious public health threat;

(46) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation;

(47) 'field safety corrective action' means corrective action taken by the 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;

(48) 'field safety notice' means the communication sent by the manufacturer to users or customers in relation to a field safety corrective action;

(49) 'market surveillance' means the activities carried out and measures taken by public authorities to ensure that products 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;

Definitions related to standards and other technical specifications:

(50) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No [.../...];

(51) 'common technical specifications' means a document other than a standard that prescribes technical requirements that provide a means to comply with the legal obligation applicable to a device, process or system.

11. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Annex XV referred to in the last subparagraph of number (1) of paragraph 1, in the light of technical progress and taking into account the similarity between a medical device and a product without a medical purpose in respect of their characteristics and risks.

12. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to adapt the definition of nanomaterial set out in number (15) of paragraph 1 in view of technical and scientific progress and taking into account definitions agreed at Union and international level.

Article 3
Regulatory status of products

13. The Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

14. The Commission shall ensure the sharing of expertise between Member States in the fields of medical devices, *in vitro* diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.

Chapter II
Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement

Article 4
Placing on the market and putting into service

15. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

16. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.

17. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 49.

18. Devices that are manufactured and used within a single health institution shall be considered as being put into service. The provisions regarding CE marking referred to in Article 18 and the obligations laid down in Articles 23 to 27 shall not apply to those devices, provided that manufacture and use of those devices occur under the health institution's single quality management system.

19. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance

requirements set out in Annex I, including the information supplied by the manufacturer.

Article 5
Distance sales

20. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation at the latest when the device is placed on the market.

21. Without prejudice to national legislation regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC or by other means of communication to a natural or legal person established in the Union shall comply with this Regulation.

Article 6
Harmonised standards

22. Devices which are in conformity with the relevant harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

The first subparagraph shall also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance plan, clinical investigations, clinical evaluation or post-market clinical follow-up.

23. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products.

Article 7
Common technical specifications

24. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, the Commission shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evaluation and post-market clinical follow-up set out in Annex XIII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).