I

(Legislative acts)

REGULATIONS

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Council Directive 90/385/EEC ([3]) and Council Directive 93/42/EEC ([4]) constitute the Union regulatory framework for medical devices, other than *in vitro* diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

(2) This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods.

([1]) Opinion of 14 February 2013 (OJ C 133, 9.5.2013, p. 52).
([2]) Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 7 March 2017 (not yet published in the Official Journal).
([3]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).
([4]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for medical devices by ensuring, among other things, that data generated in clinical investigations are reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

(3) This Regulation does not seek to harmonise rules relating to the further making available on the market of medical devices after they have already been put into service such as in the context of second-hand sales.

(4) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding medical devices should be introduced, to improve health and safety.

(5) To the extent possible, guidance developed for medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative, the International Medical Devices Regulators Forum (IMDRF), should be taken into account to promote the global convergence of regulations which contributes to a high level of safety protection worldwide, and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations.

(6) For historical reasons, active implantable medical devices, covered by Directive 90/385/EEC, and other medical devices, covered by Directive 93/42/EEC, were regulated in two separate legal instruments. In the interest of simplification, both directives, which have been amended several times, should be replaced by a single legislative act applicable to all medical devices other than *in vitro* diagnostic medical devices.

(7) The scope of application of this Regulation should be clearly delimited from other Union harmonisation legislation concerning products, such as *in vitro* diagnostic medical devices, medicinal products, cosmetics and food. Therefore, Regulation (EC) No 178/2002 of the European Parliament and of the Council [1] should be amended to exclude medical devices from its scope.

(8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. In order to ensure consistent qualification decisions in that regard across all Member States, particularly with regard to borderline cases, the Commission should be allowed to, on its own initiative or at the duly substantiated request of a Member State, having consulted the Medical Device Coordination Group ('MDCG'), decide on a case-by-case basis whether or not a specific product, category or group of products falls within the scope of this Regulation. When deliberating on the regulatory status of products in borderline cases involving medicinal products, human tissues and cells, biocidal products or food products, the Commission should ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency and the European Food Safety Authority, as relevant.

(9) Since in some cases it is difficult to distinguish between medical devices and cosmetic products, the possibility of taking a Union-wide decision regarding the regulatory status of a product should also be introduced in Regulation (EC) No 1223/2009 of the European Parliament and of the Council [2].

(10) Products which combine a medicinal product or substance and a medical device are regulated either under this Regulation or under Directive 2001/83/EC of the European Parliament and of the Council. [3] The two legislative acts should ensure appropriate interaction in terms of consultations during pre-market assessment, and of exchange of information in the context of vigilance activities involving such combination products. For medicinal products that integrate a medical device part, compliance with the general safety and performance requirements laid down in this Regulation for the device part should be adequately assessed in the context of the marketing authorisation for such medicinal products. Directive 2001/83/EC should therefore be amended.

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[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

[2] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

[3] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(11) Union legislation, in particular Regulation (EC) No 1394/2007 of the European Parliament and of the Council ([1]) and Directive 2004/23/EC of the European Parliament and of the Council ([2]), is incomplete in respect of certain products manufactured utilising derivatives of tissues or cells of human origin that are non-viable or are rendered non-viable. Such products should come under the scope of this Regulation, provided they comply with the definition of a medical device or are covered by this Regulation.

(12) Certain groups of products for which a manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risks profile should be covered by this Regulation. In order for manufacturers to be able to demonstrate the conformity of such products, the Commission should adopt common specifications at least with regard to application of risk management and, where necessary, clinical evaluation regarding safety. Such common specifications should be developed specifically for a group of products without an intended medical purpose and should not be used for conformity assessment of the analogous devices with a medical purpose. Devices with both a medical and a non-medical intended purpose should fulfil both the requirements applicable to devices with, and to devices without, an intended medical purpose.

(13) As is the case for products that contain viable tissues or cells of human or animal origin, that are explicitly excluded from Directives 90/385/EEC and 93/42/EEC and hence from this Regulation, it should be clarified that products that contain or consist of viable biological materials or viable organisms of another origin in order to achieve or support the intended purpose of those products are not covered by this Regulation either.

(14) The requirements laid down in Directive 2002/98/EC of the European Parliament and of the Council ([3]) should continue to apply.

(15) There is scientific uncertainty about the risks and benefits of nanomaterials used for devices. In order to ensure a high level of health protection, free movement of goods and legal certainty for manufacturers, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU ([4]), with the necessary flexibility to adapt that definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of devices, manufacturers should take special care when using nanoparticles for which there is a high or medium potential for internal exposure. Such devices should be subject to the most stringent conformity assessment procedures. In preparation of implementing acts regulating the practical and uniform application of the corresponding requirements laid down in this Regulation, the relevant scientific opinions of the relevant scientific committees should be taken into account.

(16) Safety aspects addressed by Directive 2014/30/EU of the European Parliament and of the Council ([5]) are an integral part of the general safety and performance requirements laid down in this Regulation for devices. Consequently, this Regulation should be considered a *lex specialis* in relation to that Directive.

(17) This Regulation should include requirements regarding the design and manufacture of devices emitting ionizing radiation without affecting the application of Council Directive 2013/59/Euratom ([6]) which pursues other objectives.

(18) This Regulation should include requirements for devices' design, safety and performance characteristics which are developed in such a way as to prevent occupational injuries, including protection from radiation.

([1]) Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

([2]) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

([3]) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components (OJ L 33, 8.2.2003, p. 30).

([4]) Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38).

([5]) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014. p. 79).

([6]) Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

(19) It is necessary to clarify that software in its own right, when 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, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

(20) The definitions in this Regulation, regarding devices themselves, the making available of devices, economic operators, users and specific processes, the conformity assessment, clinical investigations and clinical evaluations, post-market surveillance, vigilance and market surveillance, standards and other technical specifications, should be aligned with well-established practice in the field at Union and international level in order to enhance legal certainty.

(21) It should be made clear that it is essential that devices offered to persons in the Union by means of information society services within the meaning of Directive (EU) 2015/1535 of the European Parliament and of the Council ([1]) and devices used in the context of a commercial activity to provide a diagnostic or therapeutic service to persons within the Union comply with the requirements of this Regulation, where the product in question is placed on the market or the service is provided in the Union.

(22) To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council ([2]) should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as those relating to quality and risk management, laid down in this Regulation.

(23) Directive 98/79/EC of the European Parliament and of the Council ([3]) 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 insufficient, the Commission should be empowered to lay down common specifications which provide a means of complying with the general safety and performance requirements, and the requirements for clinical investigations and clinical evaluation and/or post-market clinical follow-up, laid down in this Regulation.

(24) Common specifications ('CS') should be developed after consulting the relevant stakeholders and taking account of European and international standards.

(25) The rules applicable to 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 ([4]) and Decision No 768/2008/EC of the European Parliament and of the Council ([5]).

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

(27) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors, building on the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the various parts of this Regulation, to enhance understanding of the requirements laid down in this Regulation and thus to improve regulatory compliance by the relevant operators.

([1]) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

([2]) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

([3]) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

([4]) 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 (OJ L 218, 13.8.2008, p. 30).

([5]) 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 (OJ L 218, 13.8.2008, p. 82).

(28) For the purpose of this Regulation, the activities of distributors should be deemed to include acquisition, holding and supplying of devices.

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

(30) Health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby address, on a non-industrial scale, the specific needs of target patient groups which cannot be met at the appropriate level of performance by an equivalent device available on the market. In that context, it is appropriate to provide that certain rules of this Regulation, as regards medical devices manufactured and used only within health institutions, including hospitals as well as institutions, such as laboratories and public health institutes that support the healthcare system and/or address patient needs, but which do not treat or care for patients directly, should not apply, since the aims of this Regulation would still be met in a proportionate manner. It should be noted that the concept of 'health institution' does not cover establishments primarily claiming to pursue health interests or healthy lifestyles, such as gyms, spas, wellness and fitness centres. As a result, the exemption applicable to health institutions does not apply to such establishments.

(31) In view of the fact that natural or legal persons can claim compensation for damage caused by a defective device in accordance with applicable Union and national law, it is appropriate to require manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability under Council Directive 85/374/EEC ([1]). Such measures should be proportionate to the risk class, type of device and the size of the enterprise. In this context, it is also appropriate to lay down rules concerning the facilitation, by a competent authority, of the provision of information to persons who may have been injured by a defective device.

(32) To ensure that devices manufactured in series production continue to be in conformity with the requirements of this Regulation and that experience from the use of the devices they manufacture is taken into account for the production process, all manufacturers should have a quality management system and a post-market surveillance system in place which should be proportionate to the risk class and the type of the device in question. In addition, in order to minimize risks or prevent incidents related to devices, manufacturers should establish a system for risk management and a system for reporting of incidents and field safety corrective actions.

(33) The risk management system should be carefully aligned with and reflected in the clinical evaluation for the device, including the clinical risks to be addressed as part of clinical investigations, clinical evaluation and post-market clinical follow up. The risk management and clinical evaluation processes should be inter-dependent and should be regularly updated.

(34) It should be ensured that supervision and control of the manufacture of devices, and the post-market surveillance and vigilance activities concerning them, are carried out within the manufacturer's organisation by a person responsible for regulatory compliance who fulfils minimum conditions of qualification.

(35) For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Union. Given that pivotal role, for the purposes of enforcement it is appropriate to make the authorised representative legally liable for defective devices in the event that a manufacturer established outside the Union has not complied with its general obligations. The liability of the authorised representative provided for in this Regulation is without prejudice to the provisions of Directive 85/374/EEC, and accordingly the authorised representative should be jointly and severally liable with the importer and the manufacturer. The tasks of an authorised representative should be defined in a written mandate. Considering the role of authorised representatives, the minimum requirements they should meet 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 person responsible for regulatory compliance.

([1]) Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

(36) 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 device.

(37) 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 arising from the need for protection of health and safety and from the need for protection of intellectual property rights provided for under Article 36 TFEU. Application of the principle of parallel trade 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 Court of Justice ([1]) in other relevant sectors and existing good practice in the field of medical devices.

(38) The reprocessing and further use of single-use devices should only take place where permitted by national law and while complying with the requirements laid down in this Regulation. The reprocessor of a single-use device should be considered to be the manufacturer of the reprocessed device and should assume the obligations incumbent on manufacturers under this Regulation. Nevertheless, Member States should have the possibility of deciding that the obligations relating to reprocessing and re-use of single-use devices within a health institution or by an external reprocessor acting on its behalf may differ from the obligations on a manufacturer described in this Regulation. In principle, such divergence should only be permitted where reprocessing and reuse of single-use devices within a health institution or by an external reprocessor are compliant with CS that have been adopted, or, in the absence of such CS, with relevant harmonised standards and national provisions. The reprocessing of such devices should ensure an equivalent level of safety and performance to that of the corresponding initial single-use device.

(39) Patients who are implanted with a device should be given clear and easily accessible essential information allowing the implanted device to be identified and other relevant information about the device, including any necessary health risk 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.

(40) 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 the placing on the market or putting into service of devices that comply with the requirements laid down in this Regulation. However, Member States should be allowed to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation.

(41) The traceability of devices by means of a Unique Device Identification system (UDI system) based on international guidance should significantly enhance the effectiveness of the post-market safety-related activities for devices, which is owing 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 falsified devices. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.

(42) The UDI system should apply to all devices placed on the market except custom-made devices, and be based on internationally recognised principles including definitions that are compatible with those used by major trade partners. In order for the UDI system to become functional in time for the application of this Regulation, detailed rules should be laid down in this Regulation.

(43) Transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, 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.

(44) One key aspect in fulfilling the objectives of this Regulation is the creation of a European database on medical devices (Eudamed) that should integrate different electronic systems to collate and process information regarding devices on the market and the relevant economic operators, certain aspects of conformity assessment, notified

([1]) Judgment of 28 July 2011 in Orifarm and Paranova, joined cases C-400/09 and C-207/10, ECLI:EU:C:2011:519.

bodies, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, including through better access to information for the public and healthcare professionals, to avoid multiple reporting requirements, to enhance coordination between Member States and 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. Within the 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 set up by Commission Decision 2010/227/EU ([1]).

(45) To facilitate the functioning of Eudamed, an internationally recognised medical device nomenclature should be available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. Furthermore, that nomenclature should be available, where reasonably practicable, free of charge also to other stakeholders.

(46) 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 a 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 to report serious adverse events, device deficiencies and related updates. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of the evaluation of such incidents and events by competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

(47) 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 ([2]) 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 ([3]) 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 Regulation (EC) No 45/2001, the Commission should be designated as the controller of Eudamed and its electronic systems.

(48) For implantable devices and for class III 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.

(49) The summary of safety and clinical performance for a device should include in particular the place of the device in the context of diagnostic or therapeutic options taking into account the clinical evaluation of that device when compared to the diagnostic or therapeutic alternatives and the specific conditions under which that device and its alternatives can be considered.

(50) 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.

(51) Notified bodies' assessments of manufacturers' technical documentation, in particular documentation on clinical evaluation, should be critically evaluated by the authority responsible for notified bodies. That evaluation should be part of the risk-based approach to the oversight and monitoring activities of notified bodies and should be based on sampling of the relevant documentation.

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

([1]) Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices (OJ L 102, 23.4.2010, p. 45).
([2]) 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 (OJ L 281, 23.11.1995, p. 31).
([3]) 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 (OJ L 8, 12.1.2001, p. 1).

(53) To increase transparency with regard to the oversight of notified bodies by national authorities, the authorities responsible for notified bodies should publish information on the national measures governing the assessment, designation and monitoring of notified bodies. In accordance with good administrative practice, this information should be kept up to date by those authorities in particular to reflect relevant, significant or substantive changes to the procedures in question.

(54) The Member State in which a notified body is established should be responsible for enforcing the requirements of this Regulation with regard to that notified body.

(55) In view, in particular, of the responsibility of Member States for the organisation and delivery of health services and medical care, they should be allowed to lay down additional requirements on notified bodies designated for the conformity assessment of devices and established on their territory as far as issues that are not regulated in this Regulation are concerned. Any such additional requirements laid down should not affect more specific horizontal Union legislation on notified bodies and equal treatment of notified bodies.

(56) For class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product, notified bodies should, except in certain cases, be obliged to request expert panels to scrutinise their clinical evaluation assessment report. Competent authorities should be informed about devices that have been granted a certificate following a conformity assessment procedure involving an expert panel. The consultation of expert panels in relation to the clinical evaluation should lead to a harmonised evaluation of high-risk medical devices by sharing expertise on clinical aspects and developing CS on categories of devices that have undergone that consultation process.

(57) For class III devices and for certain class IIb devices, a manufacturer should be able to consult voluntarily an expert panel, prior to that manufacturer's clinical evaluation and/or investigation, on its clinical development strategy and on proposals for clinical investigations.

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

(59) Rules under the old regime applied to invasive devices do not sufficiently take account of the level of invasiveness and potential toxicity of certain devices which are introduced into the human body. In order to obtain a suitable risk-based classification of devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body, it is necessary to introduce specific classification rules for such devices. The classification rules should take into account the place where the device performs its action in or on the human body, where it is introduced or applied, and whether a systemic absorption of the substances of which the device is composed, or of the products of metabolism in the human body of those substances occurs.

(60) The conformity assessment procedure for class I devices should be carried out, as a general rule, under the sole responsibility of manufacturers in view of the low level of vulnerability associated with such devices. For class IIa, class IIb and class III devices, an appropriate level of involvement of a notified body should be compulsory.

(61) The conformity assessment procedures for devices should be further strengthened 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.

(62) It is appropriate that certificates of free sale contain information that makes it possible to use Eudamed in order to obtain information on the device, in particular with regard to whether it is on the market, withdrawn from the market or recalled, and on any certificate on its conformity.

(63) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on clinical data that, for class III devices and implantable devices should, as a general rule, be sourced from clinical investigations that have been carried out under the responsibility of a sponsor. It should be possible both for the manufacturer and for another natural or legal person to be the sponsor taking responsibility for the clinical investigation.

(64) The rules on clinical investigations should be in line with well-established 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, so as to make it easier for the results of clinical investigations conducted in the Union to be accepted as documentation outside the Union and to make it easier for the results of clinical investigations conducted outside the Union in accordance with international guidelines to be accepted within the Union. In addition, the rules should be in line with the most recent version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

(65) It should be left to the Member State where a clinical investigation is to be conducted to determine the appropriate authority to be involved in the assessment of the application to conduct a clinical investigation and to organise the involvement of ethics committees within the timelines for the authorisation of that clinical investigation as set out in this Regulation. Such decisions are a matter of internal organisation for each Member State. In that context, Member States should ensure the involvement of laypersons, in particular patients or patients' organisations. They should also ensure that the necessary expertise is available.

(66) Where, in the course of a clinical investigation, harm caused to a subject leads to the civil or criminal liability of the investigator or the sponsor being invoked, the conditions for liability in such cases, including issues of causality and the level of damages and sanctions, should remain governed by national law.

(67) An electronic system should be set up at Union level to ensure that every clinical investigation is recorded and reported 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 ('the Charter'), 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 should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use.

(68) Where a clinical investigation is to be conducted in more than one Member State, the sponsor should have the possibility of submitting 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 that clinical investigation, the procedure for the assessment of such single application should be coordinated between the Member States under the direction of a coordinating Member State. Such coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical investigation, including informed consent. For an initial period of seven years from the date of application of this Regulation, Member States should be able to participate on a voluntary basis in the coordinated assessment. After that period, all Member States should be obliged to participate in the coordinated assessment. The Commission, based on the experience gained from the voluntary coordination between Member States, should draw up a report on the application of the relevant provisions regarding the coordinated assessment procedure. In the event that the findings of the report are negative, the Commission should submit a proposal to extend the period of participation on a voluntary basis in the coordinated assessment procedure.

(69) Sponsors should report certain adverse events and device deficiencies that occur during clinical investigations to the Member States in which those clinical investigations are being conducted. Member States should have the possibility of terminating or suspending the investigations or revoking the authorisation for those investigations, if considered necessary to ensure a high level of protection of the subjects participating in a clinical investigation. Such information should be communicated to the other Member States.

(70) The sponsor of a clinical investigation should submit a summary of results of the clinical investigation that is easily understandable for the intended user together with the clinical investigation report, where applicable, within the timelines laid down in this Regulation. Where it is not possible to submit the summary of the results within the defined timelines for scientific reasons, the sponsor should justify this and specify when the results will be submitted.

(71) This Regulation should cover clinical investigations intended to gather clinical evidence for the purpose of demonstrating conformity of devices and should also lay down basic requirements regarding ethical and scientific assessments for other types of clinical investigations of medical devices.

(72) Incapacitated subjects, minors, pregnant women and breastfeeding women require specific protection measures. However, it should be left to Member States to determine the legally designated representatives of incapacitated subjects and minors.

(73) The principles of replacement, reduction and refinement in the area of animal experimentation laid down in the Directive 2010/63/EU of the European Parliament and of the Council [1] should be observed. In particular, the unnecessary duplication of tests and studies should be avoided.

(74) Manufacturers should play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices in order to update their technical documentation and cooperate with the national competent authorities in charge of vigilance and market surveillance activities. To this end, manufacturers should establish a comprehensive post-market surveillance system, set up under their quality management system and based on a post-market surveillance plan. Relevant data and information gathered through post-market surveillance, as well as lessons learned from any implemented preventive and/or corrective actions, should be used to update any relevant part of technical documentation, such as those relating to risk assessment and clinical evaluation, and should also serve the purpose of transparency.

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

(76) Member States should take appropriate measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents. Healthcare professionals, users and patients should be encouraged and enabled to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers of any suspected serious incidents and, where a manufacturer confirms that such an incident has occurred, the authorities concerned should ensure that appropriate follow-up action is taken in order to minimise recurrence of such incidents.

(77) The evaluation 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.

(78) In the context of the investigation of incidents, the competent authorities should take into account, where appropriate, the information provided by and views of relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.

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

(80) 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.

(81) Any statistically significant increase in the number or severity of incidents that are not serious or in expected side-effects that could have a significant impact on the benefit-risk analysis and which could lead to unacceptable risks should be reported to the competent authorities in order to permit their assessment and the adoption of appropriate measures.

(82) 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 including *in vitro* diagnostic medical devices, should be established to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) 2017/746 of the European Parliament and of the Council [2], to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. The MDCG should be able to establish subgroups in order to have access to necessary in-depth

[1] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (see page 176 of this Official Journal).

technical expertise in the field of medical devices including *in vitro* diagnostic medical devices. When establishing subgroups, appropriate consideration should be given to the possibility of involving existing groups at Union level in the field of medical devices.

(83) Expert panels and expert laboratories should be designated by the Commission on the basis of their up-to-date clinical, scientific or technical expertise, with the aim of providing scientific, technical and clinical assistance to the Commission, the MDCG, manufacturers and notified bodies in relation to the implementation of this Regulation. Moreover, expert panels should fulfil the tasks of providing an opinion on clinical evaluation assessment reports of notified bodies in the case of certain high-risk devices.

(84) Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is essential for ensuring a consistently high level of health and safety protection within the internal market, in particular in the areas of clinical investigations and vigilance. The principle of coordinated exchange and assessment should also apply across other authority activities described in this Regulation, such as the designation of notified bodies and should be encouraged in the area of market surveillance of devices. Joint working, coordination and communication of activities should also lead to more efficient use of resources and expertise at national level.

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

(86) The Union and, where appropriate, the Member States 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 that promote the adoption in other jurisdictions of regulations that lead to a level of health and safety protection equivalent to that set by this Regulation.

(87) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement.

(88) Whilst this Regulation should not affect the right of Member States to levy fees for activities at national level, Member States should, in order to ensure transparency, inform the Commission and the other Member States before they decide on the level and structure of such fees. In order to further ensure transparency, the structure and level of the fees should be publicly available on request.

(89) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter and in particular 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.

(90) The power to adopt delegated acts in accordance with Article 290 TFEU should be delegated to the Commission in order to amend certain non-essential provisions of this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([1]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with preparation of delegated acts.

(91) 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 ([2]).

([1]) OJ L 123, 12.5.2016, p. 1.
([2]) 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 (OJ L 55, 28.2.2011, p. 13).

(92) The advisory procedure should be used for implementing acts that set out the form and presentation of the data elements of manufacturers' summaries of safety and clinical performance, and that establish the model for certificates of free sale, given that such implementing acts are of a procedural nature and do not directly have an impact on health and safety at Union level.

(93) 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, imperative grounds of urgency so require.

(94) In order to enable it to designate issuing entities, expert panels and expert laboratories, implementing powers should be conferred on the Commission.

(95) To allow economic operators, especially SMEs, notified bodies, Member States and the Commission to adapt to the changes introduced by this Regulation and to ensure its proper application, it is appropriate to provide for a sufficient transitional period for that adaptation and for the organisational arrangements that are to be made. However, certain parts of the Regulation that directly affect Member States and the Commission should be implemented as soon as possible. It is also particularly important that, by the date of application of this Regulation, a sufficient number of notified bodies be designated in accordance with the new requirements so as to avoid any shortage of medical devices on the market. Nonetheless, it is necessary that any designation of a notified body in accordance with the requirements of this Regulation prior to the date of its application be without prejudice to the validity of the designation of those notified bodies under Directives 90/385/EEC and 93/42/EEC and to their capacity to continue issuing valid certificates under those two Directives until the date of application of this Regulation.

(96) In order to ensure a smooth transition to the new rules for registration of devices and of certificates, the obligation to submit the relevant information to the electronic systems set up at Union level pursuant to this Regulation should, in the event that the corresponding IT systems are developed according to plan, only become fully effective from 18 months after the date of application of this Regulation. During this transitional period, certain provisions of Directives 90/385/EEC and 93/42/EEC should remain in force. However, in order to avoid multiple registrations, economic operators and notified bodies who register in the relevant electronic systems set up at Union level pursuant to this Regulation should be considered to be in compliance with the registration requirements adopted by the Member States pursuant to those provisions.

(97) In order to provide for a smooth introduction of the UDI system, the moment of application of the obligation to place the UDI carrier on the label of the device should vary from one to five years after the date of application of this Regulation depending upon the class of the device concerned.

(98) 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. Manufacturers' obligations as regards the making available of documentation regarding devices they placed on the market and manufacturers' and Member States' obligations as regards vigilance activities for devices placed on the market pursuant to those Directives should however continue to apply. While it should be left to Member States to decide how to organise vigilance activities, it is desirable for them to have the possibility of reporting incidents related to devices placed on the market pursuant to the Directives using the same tools as those for reporting on devices placed on the market pursuant to this Regulation. It is furthermore appropriate, in order to ensure a smooth transition from the old regime to the new regime, to provide that Commission Regulation (EU) No 207/2012 ([1]) and Commission Regulation (EU) No 722/2012 ([2]) should remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation.

([1]) Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28).

([2]) Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 212, 9.8.2012, p. 3).

Decision 2010/227/EU adopted in implementation of those Directives and Directive 98/79/EC should also remain in force and continue to apply until the date when Eudamed becomes fully functional. Conversely, no such maintenance in force is required for Commission Directives 2003/12/EC ([1]) and 2005/50/EC ([2]) and Commission Implementing Regulation (EU) No 920/2013 ([3]).

(99) The requirements of this Regulation should be applicable to all devices placed on the market or put into service from the date of application of this Regulation. However, in order to provide for a smooth transition it should be possible, for a limited period of time from that date, for devices to be placed on the market or put into service by virtue of a valid certificate issued pursuant to Directive 90/385/EEC or pursuant to Directive 93/42/EEC.

(100) The European Data Protection Supervisor has given an opinion ([4]) pursuant to Article 28(2) of Regulation (EC) No 45/2001.

(101) Since the objectives of this Regulation, namely to ensure the smooth functioning of the internal market as regards medical devices and 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 be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, 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 those objectives.