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 (Text with EEA relevance)

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

(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) Directive 98/79/EC of the European Parliament and of the Council[(3)] constitutes the Union regulatory framework for *in vitro* diagnostic medical devices. However, a fundamental revision of that Directive is needed to establish a robust, transparent, predictable and sustainable regulatory framework for *in vitro* diagnostic 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 *in vitro* diagnostic 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 *in vitro* diagnostic 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 *in vitro* diagnostic medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for *in vitro* diagnostic medical devices by ensuring, among other things, that data generated in

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performance studies are reliable and robust and that the safety of subjects participating in performance studies is protected.

(3) This Regulation does not seek to harmonise rules relating to the further making available on the market of *in vitro* diagnostic 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, risk classification, conformity assessment procedures, performance evaluation and performance studies, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding *in vitro* diagnostic medical devices should be introduced, to improve health and safety.

(5) To the extent possible, guidance developed for *in vitro* diagnostic medical devices at international level, in particular in the context of the Global Harmonization Task Force and its follow-up initiative, the International Medical Devices Regulators Forum, 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 evidence.

(6) There are specific features of *in vitro* diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the *in vitro* diagnostic medical device sector which require the adoption of specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned.

(7) The scope of application of this Regulation should be clearly delimited from other legislation concerning products, such as medical devices, general laboratory products and products for research use only.

(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, the European Chemicals Agency and the European Food Safety Authority, as relevant.

(9) It appears that it is possible that divergent national rules regarding the provision of information and counselling in relation to genetic testing might only have an impact on the smooth functioning of the internal market to a limited extent. Therefore, it is appropriate to lay down only limited requirements in this regard in this Regulation,

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having regard to the need to ensure constant respect of the principles of proportionality and subsidiarity.

(10) It should be made clear that all tests that provide information on the predisposition to a medical condition or a disease, such as genetic tests, and tests that provide information to predict treatment response or reactions, such as companion diagnostics, are *in vitro* diagnostic medical devices.

(11) Companion diagnostics are essential for defining patients' eligibility for specific treatment with a medicinal product through the quantitative or qualitative determination of specific markers identifying subjects at a higher risk of developing an adverse reaction to the medicinal product in question or identifying patients in the population for whom the therapeutic product has been adequately studied, and found safe and effective. Such biomarker or biomarkers can be present in healthy subjects and/or in patients.

(12) Devices that are used with a view to monitoring treatment with a medicinal product in order to ensure that the concentration of relevant substances in the human body is within the therapeutic window are not considered to be companion diagnostics.

(13) The requirement to reduce risks as far as possible should be fulfilled taking into account the generally acknowledged state of the art in the field of medicine.

(14) Safety aspects addressed by Directive 2014/30/EU of the European Parliament and of the Council[(4)] 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.

(15) 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[(5)] which pursues other objectives.

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

(17) 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 an *in vitro* diagnostic medical device, qualifies as an *in vitro* diagnostic medical device, while software for general purposes, even when used in a healthcare setting, or software intended for well-being purposes is not an *in vitro* diagnostic 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.

(18) The definitions in this Regulation regarding the devices themselves, the making available of devices, economic operators, users and specific processes, the conformity assessment, clinical evidence, 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.

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(19) 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[(6)] 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.

(20) To recognise the important role of standardisation in the field of *in vitro* diagnostic medical devices, compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council[(7)] 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.

(21) Directive 98/79/EC 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 performance studies and performance evaluation and/or post-market follow-up, laid down in this Regulation.

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

(23) 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[(8)] and Decision No 768/2008/EC of the European Parliament and of the Council[(9)].

(24) 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.

(25) 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.

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

(27) Several of the obligations on manufacturers, such as performance evaluation or vigilance reporting, that were set out only in the Annexes to Directive 98/79/EC, should be incorporated into the enacting provisions of this Regulation to facilitate its application.

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(28) To ensure the highest level of health protection, the rules governing *in vitro* diagnostic medical devices, manufactured and used within a single health institution only, should be clarified and strengthened. That use should be understood to include measurement and delivery of results.

(29) Health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby addressing, 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 devices manufactured and used only within health institutions, including hospitals as well as institutions, such as laboratories and public health institutes that support the health care 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.

(30) 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[(10)]. 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.

(31) 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 incidents and field safety corrective actions.

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

(33) It should be ensured that supervision and control of the manufacture of devices, as well as 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.