

The EU's In Vitro Diagnostics (IVD) Regulation:

a summary of the regulatory requirements for
software and genetic tests



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The European Union (EU)'s In Vitro Diagnostics (IVD) Regulation (of 5 April 2017)¹ regulates the placing on the market in the EU of "in vitro" medical devices (IVDs). IVDs include software (health apps) and genetic tests, which examine specimens from the human body to seek to predict or diagnose disease. The IVD Regulation is relevant to the feedback of results to patients from Big Data research (statistical analysis of medical records, including medical test results), as the software which makes the diagnosis, or predicts disease risk or drug response, is likely to count as a medical device and will therefore be regulated to ensure it provides the claimed benefits and is safe. If genetic test results (specific tests, or whole genomes) are used for a medical purpose, these will also be covered by the IVD Regulation.

The Regulation enters into force by 26 May 2022. From this date, only devices which meet certain scientific and technical requirements will be allowed to be placed on the EU market. Manufacturers will need to provide clinical evidence that devices meet these requirements, which will be assessed before the device is awarded a CE Mark. However, there will be some exemptions, particularly for tests developed and used in a healthcare institution without the involvement of commercial companies.

The IVD Regulation replaces the existing IVD Directive. Although the Directive required devices to be CE marked before placing on the market, the regulatory requirements were weak for most devices, with no clinical evidence required. The requirements change significantly with the new Regulation, which requires clinical evidence to demonstrate the claimed benefits and safety of the device, in relation to its stated purpose, and ongoing post-market follow-up to ensure conformity.

The main requirement for the company or institution which places the software or test on the market is to produce a technical dossier which includes clinical information such as the positive predictive value of the test (where relevant), and which demonstrates laboratory quality assurance and quality management. This dossier will be assessed by "notified bodies" which must award the test a CE mark before it can be placed on the market (including if the test is sold via the internet or by overseas companies). To collect the information required for the dossier, companies may need to conduct clinical studies. In many cases, these studies will need to be registered in advance with an EU member state. There are also requirements for post-market monitoring, updating of technical information, and the reporting of adverse events.

There are specific requirements for the clinical studies used to comply with the IVD Regulation, covering issues such as ethical oversight and scientific protocols. These include requirements for fully informed consent to studies which require invasive procedures, carry other risks, or where the test results may influence patient management decisions and/or may be used to guide treatment. However, there is an exemption for "performance studies involving companion diagnostics using only left-over samples", which require only notification

to the competent authority (and compliance with general requirements, including data protection law). Companion diagnostics are those used to identify patients most likely to benefit from, or most at risk from, medicinal products.

The regulation requires new databases to be set up to track which devices are CE marked and to register clinical studies and post-market monitoring. Although much information will be submitted in confidence to regulators, summaries of safety and performance will be publicly available and more detailed information may be released to a patient or their insurance company if there is reason to believe they have been harmed by a device.

Companies will be required to take out liability insurance, and penalties for breaches of the regulation will be set by EU Member States.

Post-Brexit, UK-based companies will need to comply with the IVD Regulation in order to market medical devices, including genetic tests and software, in the EU from May 2022. The UK regulator, the Medicines and Healthcare Regulatory Agency (MHRA) is involved in preparations to implement equivalent regulations in the UK. However, the details of future regulation in the UK remain unclear at the current time.

This briefing outlines the requirements of the IVD Regulation.

1. Definition of an In Vitro Medical Device (IVD)

The Regulation covers medical devices, which have a “specific medical purpose”, as defined in point (1) of Article 2 of Regulation (EU) 2017/745.² More specifically (Article 2):

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

- (a) concerning a physiological or pathological process or state;*
- (b) concerning congenital physical or mental impairments;*
- (c) concerning the predisposition to a medical condition or a disease;*
- (d) to determine the safety and compatibility with potential recipients;*
- (e) to predict treatment response or reactions;*
- (f) to define or monitoring therapeutic measures.*

Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices;”

Thus, software or genetic tests which claim to predict disease risk or drug response, or diagnose a medical condition, clearly fall within the scope of the Regulation, whilst genetic ancestry or paternity tests do not. Genetic tests or software that aims to predict the body’s response to diet or exercise are more of a grey area. Manufacturers often refer to such tests as “lifestyle” tests. However there is no definition of a lifestyle test and it could be argued that devices that provide individually tailored advice on diet or exercise may have a medical purpose.

The term “well-being purposes” is used in Recital (17), however this is not defined:

“(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”.

Under Article 2, the European Commission shall determine whether or not a specific product, or category or group of products, falls within the definitions, after consulting the Medical Device Coordination Group (MDCG). The Commission may do this using implementing acts: either on its own initiative, or when requested by a Member State.

2. Classification of devices

The IVD Regulation adopts a risk-based approach to regulation, with more onerous requirements for riskier devices (Class D devices) and the least oversight for the least risky devices (class A). The risk classifications are given in Annex VIII. In brief, Class D includes devices which test for infectious diseases such as HIV, plus some blood typing tests; Class C includes human genetic tests, companion diagnostics and self-testing; Class A includes products for lab use, instruments and receptacles (e.g. for collection blood or saliva); and Class B includes all other devices. Software with a device is classified with that device (e.g. software that calculates genetic risks from a human genetic test, including whole genome sequencing, would be Class C); otherwise software is classified in its own right according to its purpose.

Relevant definitions in Article 2 include:

“(5) ‘device for self-testing’ means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services;

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

(7) ‘companion diagnostic’ means a device which is essential for the safe and effective use of a corresponding medicinal product to: (a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product;”

In the EU, Article 1(2) of Directive 2001/83/EC³ establishes the following definition of medicinal product:

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

According to settled case law of the European Court of Justice (ECJ), 'a product is a medicinal product if it falls within either of those two definitions'.³ Further, when there is uncertainty over the classification of a product, the stricter regime of medicinal products applies. Thus, “borderline products” such as food products/food supplements and medical devices can be expected to fall under the definition of “medicinal products”. This means that human genetic tests or software used to make recommendations regarding supplements, functional foods, or further medical testing may be classed as “companion diagnostics”.

Article 47 requires any dispute between the manufacturer and the notified body about the risk classification to be referred for a decision to the competent authority of the Member

State in which the manufacturer (or its authorised representative) has its registered place of business. The European Commission also has powers to adopt implementing acts to clarify application of Annex VIII to a given device, or category or group of devices, or to reclassify devices in the light of new evidence.

A major difference between the current IVD Directive and the new IVD Regulation is that the majority of devices (classes B, C and D) require clinical evidence to be supplied by the manufacturer to demonstrate the benefits and safety of the device. This includes genetic tests (Class C).

3. Conditional exemption for devices manufactured and used in healthcare institutions

The main exemption in the Regulation is for devices manufactured and used in healthcare institutions as specified in Article 5.5:

“5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

- (a) the devices are not transferred to another legal entity;*
- (b) manufacture and use of the devices occur under appropriate quality management systems;*
- (c) the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation;*
- (d) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market;*
- (e) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;*
- (f) the health institution draws up a declaration which it shall make publicly available, including: (i) the name and address of the manufacturing health institution, (ii) the details necessary to identify the devices, (iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor;*
- (g) as regards class D devices in accordance with the rules set out in Annex VIII, the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met. Member States may apply this provision also to class A, B or C devices in accordance with the rules set out in Annex VIII;*
- (h) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (g); and*
- (i) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.*

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

This paragraph shall not apply to devices that are manufactured on an industrial scale.”

This exemption is intended to reduce the regulatory burden on hospitals which manufacture and use their own tests, often for relatively small patient groups when no commercial product is available on the market. Important restrictions include the condition that the devices are not transferred to another legal entity (such as a commercial company) and that they are not manufactured on a commercial scale. In addition, such devices must meet the relevant general safety and performance requirements set out in Annex I, documentation must be kept (with more onerous requirements for Class D devices), quality assurance and quality management must be in place, and the health institution must learn from experience.

Recital (29) provides some further clarification:

“(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.”

4. Who are the regulators?

The Regulation envisages roles for:

- The competent authorities (CAs) of Member States (such as the UK’s Medicines and Healthcare Regulatory Authority, MHRA, whilst the UK remains in the EU);
- A new advisory body called the Medical Device Coordination Group (MDCG);
- The European Commission;
- Notified Bodies (meaning a conformity assessment body designated in accordance with the Regulation)
- The European Medicines Agency (EMA).

The bulk of the regulatory work will be undertaken by the notified bodies, which are set up according to Articles 31-46 (Chapter IV), and which assess the technical documentation submitted by manufacturers and certify devices. The notified bodies in each Member State are overseen by that country’s Competent Authority (CA), which must also review some notified body assessments (Article 41). The Regulation introduces specific requirements for notified bodies (for example, in relation to conflicts of interest and professional qualifications, Article 67 and Annex VII) in an attempt to address concerns that such bodies may otherwise act essentially as consultancies to manufacturers.

The European Commission has extensive powers to adopt implementing acts, particularly with a view to resolving differences of interpretation or specifying common standards (Articles 3, 5, 9, 24, 29, 32, 35, 38, 41, 43, 44, 47, 48, 54, 55, 56, 66, 74, 77, 86, 91, 92, 93, 100, 105). It is required to consult the MDCG on some issues. The Commission, with the MDCG, must also investigate all cases where concerns have been brought to their attention regarding a notified body (Article 43).

The EMA plays a consultative role regarding the regulatory status of devices (Article 3). It may also be consulted in the case of companion diagnostics (Articles 48 and 84).

5. What are the requirements for placing a device on the market?

Article 5 covers placing on the market and putting into service. The definitions are given in Article 2:

“(21) ‘placing on the market’ means the first making available of a device, other than a device for performance study, on the Union market;

(22) ‘putting into service’ means the stage at which a device, other than a device for performance study, 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;”

According to Article 5, 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. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose; and demonstration of conformity with the general safety and performance requirements shall include a performance evaluation in accordance with Article 56.

Devices that are in conformity relevant harmonised standards will be presumed to be in conformity with the requirements of the Regulation (Article 8) or, where such standards do not exist, the Commission may adopt Common Specifications (Article 9).

The general obligations of manufacturers are given in Article 10. These include: having a risk management system, conducting a performance evaluation (as set out in Article 56 and Annex XIII, including Post-Market Performance Follow-Up), keeping up-to-date technical documentation, registering the test and obtaining a CE mark, having a quality management system, supplying the relevant information to users and regulators, and taking corrective actions in the event of non-compliance.

According to Article 56 (Performance evaluation and clinical evidence), the manufacturer shall specify and justify the level of the clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. This involves a performance evaluation to obtain clinical evidence to support the intended purpose of the device as stated by the manufacturer and demonstrate: (a) scientific validity; (b) analytical performance; (c) clinical performance. The data and conclusions drawn from the assessment of those elements shall constitute the clinical evidence for the device and show that the intended clinical benefit(s) will be achieved and that the device is safe. The performance evaluation and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's Post-Market Performance Follow-Up (PMPF) plan.

Devices manufactured and used only within health institutions and meeting the conditions given in Article 5.5, need only meet the relevant general safety and performance requirements set out in Annex I. This requires a self-declaration of conformity by the health institution.

Article 48 outlines the conformity assessment procedure for other devices, with class B, C and D devices all requiring assessment of technical documentation by a notified body. Technical documentation must be provided as outlined in Annex II, including the device description and specification, labels, design and manufacturing information, information for the demonstration of conformity with the general safety and performance requirements, the benefit-risk analysis, analytical performance and stability. For software, for example, the documentation should typically include the summary results of all verification, validation and testing performed in-house and applicable in an actual user environment prior to final

release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling. The documentation must contain the performance evaluation report, which includes the reports on the scientific validity, the analytical and the clinical performance, as referred to in Annex XIII, together with an assessment of those reports.

Details regarding the general safety and performance requirements are given in Annex I. Devices should achieve the performances stated by the manufacturer and be maintained during the lifetime of the device. The clinical performance may include diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, and expected values in normal and affected populations.

To demonstrate the scientific validity and the analytical and clinical performance, Annex XIII (1.2) requires manufacturers to:

- identify through a systematic scientific literature review the available data relevant to the device and its intended purpose and identify any remaining unaddressed issues or gaps in the data;
- appraise all relevant data by evaluating their suitability for establishing the safety and performance of the device;
- generate any new or additional data necessary to address outstanding issues.

Types of evidence that may be submitted include scientific (peer-reviewed) literature, consensus expert opinions/positions from relevant professional associations, published experience, and the results of further studies.

The applicable conformity assessment procedures are set out in Annexes IX to XI. Conformity assessment may be based on a quality management system and assessment of technical documentation (Annex IX), or manufacturers instead may choose to apply Annex X (Conformity Assessment Based on Type-Examination) and Annex XII (Conformity Assessment Based on Production Quality Assurance). The evidence required depends on the risk classification and some other aspects of the device (such as whether it is used for self-testing, whether it is a companion diagnostic, and whether it is sterile). Class A (low risk) devices require only a self-declaration of conformity.

Following conformity assessments by notified bodies, certificates of conformity are issued (Article 51), which are valid for 5 years, the device is CE marked, and a Certificate of free sale is issued (Article 55). The content of certificates is given in Annex XII. Notified bodies may impose restrictions on the intended purpose or users, and/or require specific post-market studies, and may suspend or withdraw certificates.

Article 54 allows for derogations from the conformity assessment procedures in the interest of public health or patient safety or health. The Commission and other Member States must be informed if this process is used for more than one patient.

6. What are the requirements for clinical studies?

Chapter VI (articles 56 to 77) covers clinical evidence, performance evaluation and performance studies.

According to Article 56, clinical performance studies shall be carried out (in accordance with Section 2 of Part A of Annex XIII) unless it is duly justified to rely on other sources of clinical performance data to provide the clinical evidence necessary to demonstrate conformity. Other sources of data given in Annex XII are scientific peer-reviewed literature or published experience gained by routine diagnostic testing.

General requirements for performance studies are given in Article 57: these include protecting the rights, safety, dignity and well-being of the subjects; ensuring the data generated are scientifically valid, reliable and robust; and conducting all studies in accordance with applicable law on data protection.

There are additional requirements for certain performance studies (Article 58). For these, there is an authorisation and registration process, and specific technical and ethical requirements, including, *inter alia*: scientific and ethical review, fully informed consent from participants (or their legally designated representative) and measures to ensure that vulnerable populations and subjects are appropriately protected. Articles 59 to 77 provide more detail on these requirements. The performance studies covered by Article 58 are those which involve surgically invasive sampling, or additional invasive procedures or other risks, or are “interventional” clinical performance studies (defined in Article 2(46) as a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment). This includes studies involving companion diagnostics. However, there is an exemption in Article 58(2) for “*performance studies involving companion diagnostics using only left-over samples*”, which require only notification to the competent authority (and compliance with the general requirements in Article 57, including data protection law). The term “*left-over samples*” is not defined.

Recital (73) states:

“It is necessary to clarify that performance studies using left-over specimens need not be authorised. Nevertheless, the general requirements and other additional requirements with regard to data protection and the requirements applicable to procedures that are performed in accordance with national law such as ethical review should continue to apply to all performance studies, including when using left-over specimens”.

7. Post-market monitoring

Chapter VII (articles 78 to 95) cover post-market surveillance, vigilance and market surveillance.

A post-market surveillance system is required for each device to gather data on the quality, performance and safety of a device throughout its entire lifetime, and to implement any resulting preventive and corrective actions. This system must be used to update information such as the performance evaluation, the (public) summary of safety and performance and the relevant technical documentation. The system should include a post-market surveillance plan, the requirements for which are set out in Section 1 of Annex III (covering e.g. collecting information on serious incidents, specialist literature, and complaints, and setting up protocols for reporting and taking corrective actions). The post-market surveillance plan is part of the technical documentation (specified in Annex II).

Manufacturers of class A and B devices must prepare a post-market surveillance report, whereas Manufacturers of class C and class D devices must prepare a periodic safety update report (PSUR) at least annually, and include it in the technical documentation for the device (Article 80). For Class D devices, PSURs are reviewed by notified bodies, but for Class C devices (including genetic tests and associated software) manufacturers are only required to make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.

Article 82 outlines requirements for reporting of serious incidents (i.e. events that may lead to death, serious deterioration of health, or a threat to public health) and taking of field safety corrective actions. Member States are required to take appropriate measures such as

organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities suspected serious incidents. The competent authorities are required to keep records of such reports, and to inform manufacturers and require a response from them (which may include corrective action). Manufacturers must also report serious incidents to the relevant competent authority.

Article 83 covers trend reporting, which should cover any statistically significant increase in the frequency or severity of incidents that are not serious incidents but that could have a significant impact on the benefit-risk analysis.

Article 84 covers the process for analysis of serious incidents and taking field safety corrective actions.

Under Article 85, the Commission, in collaboration with the Member States, is required to put in place systems and processes to actively monitor the data available in the electronic system on vigilance and post-market surveillance (set up as part of the Eudamed database), in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

The Commission may adopt implementing acts covering the detailed arrangements and procedural aspects for reporting and corrective actions (Article 86) and must set up and manage an electronic system on vigilance and post-market surveillance, in collaboration with Member States (Article 87).

Article 88 requires market surveillance by competent authorities. This involves appropriate checks on the conformity characteristics and performance of devices e.g. a review of documentation and physical or laboratory checks on the basis of adequate samples. Competent authorities may make unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users.

Article 89 covers the evaluation of devices suspected of presenting an unacceptable risk or other non-compliance and Article 90 covers the procedure for dealing with devices presenting an unacceptable risk to health and safety.

8. Specific requirements for human genetic tests

Article 4 covers genetic information, counselling and informed consent. It requires that an individual being genetically tested for medical purposes in the context of healthcare (or, where applicable, his or her legally designated representative) is provided with relevant information on the nature, the significance and the implications of the genetic test, as appropriate. Member States are required to ensure that there is appropriate access to counselling in the case of genetic tests that provide information on genetic predisposition for untreatable medical conditions and/or diseases (unless a diagnosis is merely being confirmed by a genetic test, or a companion diagnostic is being used). The Regulation states that nothing in this Article prevents Member States from adopting or maintaining more protective national measures.

Article 1 includes:

8. This Regulation shall not affect the right of a Member State to restrict the use of any specific type of device in relation to aspects not covered by this Regulation.

9. This Regulation shall not affect national law concerning the organisation, delivery or financing of health services and medical care, such as the requirement that certain devices may only be supplied on a medical prescription, the requirement that only certain health professionals or health care institutions may dispense or use certain devices or that their use be accompanied by specific professional counselling.

Thus, the Regulation does not overturn the bans in place in some EU countries on “direct to consumer” (DTC) sales of medical genetic tests, or prevent further countries banning DTC testing in the future, although no such ban is implemented at the EU level.

9. Liability and penalties

Article 10(15) states:

Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law. Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

Where the manufacturer is not established in a Member State, the authorised representative is legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer (Article 11(15)).

In addition, the notified body is required to take out appropriate liability insurance for its conformity assessment activities, unless liability is assumed by the Member State in question in accordance with national law or that Member State is directly responsible for their conformity assessment (Annex VII, 1.4).

Regarding penalties for infringement of the Regulation, Article 106 states:

The Member States shall lay down the rules on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive. The Member States shall notify the Commission of those rules and of those measures by 25 February 2022 and shall notify it without delay of any subsequent amendment affecting them.

10. Databases, information and reporting

Article 7 requires that claims made by the manufacturer may not mislead the user or the patient with regard to the device's intended purpose, safety and performance. This includes suggesting uses other than the intended purposes or failing to inform of a likely risk.

Chapter III of the Regulation (Articles 22 to 30) outlines the requirements for the identification, traceability and registration of devices. A Unique Device Identification (UDI) system will be set up, and the UDI will need to be included on the label or packaging of the device, as well as in a UDI database. Member States shall encourage, and may require, health care professionals to store and keep the UDI of the devices with which they have been supplied with (Article 24). The manufacturer is responsible for providing the UDI and the other core data elements referred to in Part B of Annex VI (including the device description and risk class) to the UDI-database.

Section 20 of Annex I specifies information that must accompany each device in the label and instructions for use (as required by Article 10). For example, the label must include specific information such as the UDI, any warnings, and whether the device is intended for self-testing or near-patient use. The instructions must include, *inter alia*, the device's intended purpose, the specific information that is intended to be provided and, where applicable, the testing population.

The Regulation also sets up a European database on medical devices (Eudamed) (Article 30). This includes the UDI database and an electronic system for registration of economic operators (manufacturers, authorised representatives and importers), as well as databases of notified bodies, post market surveillance and clinical studies. Article 87 requires the Commission to ensure that healthcare professionals and the public have appropriate levels of access to the electronic system on vigilance and post-market surveillance.

The manufacturer must provide the information referred to in Section 2 of Part A of Annex VI to Eudamed and keep it updated (Article 26(3)). This information includes, *inter alia*, the risk class of the device; the single identification number of the performance study, if applicable; the summary of safety and performance for class C or D devices; the status of the device and whether it is 'new' or intended for self-testing or near-patient testing. The summary of safety and performance is to be made public and written in a way that is clear to the intended user and, if relevant, to the patient (Article 29). It must include the summary of the performance evaluation as referred to in Annex XIII, and relevant information on the Post Market Performance Follow-up (PMPF), as well as information on any residual risks and any undesirable effects, warnings and precautions. The Commission may set out the form and the presentation of the data elements to be included in the summary of safety and performance, by means of implementing acts.

According to Article 10(13), if a competent authority considers or has reason to believe that a device has caused damage, it shall, upon request, facilitate the provision of the relevant information and documentation to the patient, their successor or insurance company “*without prejudice to data protection rules and, unless there is an overriding public interest in disclosure, without prejudice to the protection of intellectual property rights*”. The competent authority need not comply with this obligation where disclosure of the information is ordinarily dealt with in the context of legal proceedings.

Nevertheless, Article 102 allows for information to be exchanged in confidence between regulators and protects commercial confidentiality. Therefore, much information provided by manufacturers to notified bodies or competent authorities will not be public.

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