STATUTORY INSTRUMENTS.

S.I. No. 256 of 2022

IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATIONS 2022

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I, Stephen Donnelly, Minister for Health, in exercise of the powers conferred on me by section 32 (as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) of the Irish Medicines Board Act 1995 (No. 29 of 1995) and for the purpose of giving full effect to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[1], as amended by Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022[2]; Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008[3] and Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019[4], hereby make the following regulations:

PART 1

PRELIMINARY

Citation

1. These Regulations may be cited as the *In Vitro* Diagnostic Medical Devices Regulations 2022.

Commencement

2. These Regulations come into operation on 26 May 2022.

Interpretation

3. (1) In these Regulations—

"approved examiner" means—

(a) a Chief Medical Scientist located at an official laboratory,
(b) a Consultant Microbiologist located at an official laboratory,
(c) a Deputy Public Analyst located at a Public Analyst's Laboratory,
(d) an Executive Analytical Chemist located at a Public Analyst's Laboratory,
(e) a Public Analyst located at a Public Analyst's Laboratory, or
(f) a person, or member of a class of persons, designated for that purpose by the Authority;

[1] OJ No. L117, 05.05.2017, p. 176.
[2] OJ No. L 19, 28.1.2022, p. 3.
[3] OJ No. L 218, 13.8.2008, p. 30.
[4] OJ No. L 169, 25.6.2019, p. 1.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 27*th May,* 2022.

"authorised officer" means—

(a) a person appointed under Regulation 26, or
(b) an officer of Customs and Excise;

"Authority" means the Health Products Regulatory Authority;

"compliance notice" mean a notice under Regulation 30;

"device" means—

(a) an *in vitro* diagnostic medical device,
(b) an accessory for an *in vitro* diagnostic medical device,

and does not include—

(i) a product or other substance excluded by Article 1(3) of the EU Regulation,
(ii) an in-house device;

"Directive" means Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998[5], as amended by Commission Directive 2011/100/EU of 20 December 2011[6];

"EU Regulation" means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[1], as amended by Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022[2];

"information society service" has the meaning assigned to it by point (b) of Article 1(1) of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015[7];

"in-house device" means a device which—

(a) is manufactured and used only within a health institution,
(b) complies with all of the conditions in Article 5(5) of the EU Regulation, and
(c) is not manufactured on an industrial scale;

"inspect" includes search;

"legally designated representative", for the purposes of these Regulations and the EU Regulation only, and in relation to performance studies only, means:

(a) in relation to an incapacitated subject who is, or is being considered as, a subject
for a performance study, means-
(i) a person, other than a person connected with the conduct of the performance study, who by virtue of his or her family or other personal relationship with the individual:

(aa) can provide the best interpretation of the will and preferences relating to healthcare of the individual based on their knowledge of the individual, and

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[5] OJ No. L331, 7.12.98, p. 1.
[6] OJ No. L341, 22.12.2011, p. 50.
[1] OJ No. L117, 05.05.2017, p. 176.
[2] OJ No. L 19, 28.1.2022, p. 3.
[7] OJ No. L 241, 17.9.2015, p. 1.

(bb) is available and willing to act for that purpose, or

(ii) if there is no such person, the medical practitioner primarily responsible for the medical treatment provided to the individual where he or she-

(aa) can provide the best interpretation of the will and preferences relating to healthcare of the individual based on their knowledge of the individual,

(bb) is not involved in the conduct of the performance study,

(cc) is of the view that participation in the performance study will not prejudice the health and wellbeing of the individual, and

(dd) is available and willing to act for that purpose, and

(b) in relation to a minor who is, or is being considered as, a subject for a performance

study means a guardian within the meaning of the Guardianship of Infants Act, 1964 (No. 7 of 1964);

"Market Surveillance Regulation" means Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019[4];

"member state" means a member state of the European Economic Area;

"Minister" means the Minister for Health;

"National Office" means the National Office for National Research Ethics Committees for Performance Studies of *In Vitro* Diagnostic Medical Devices established by Regulation 4 of the European Union (National Research Ethics Committees for Performance Studies of *In Vitro* Diagnostic Medical Devices) Regulations 2022;

"National REC" means a National Research Ethics Committee established pursuant to Regulation 11 of the European Union (National Research Ethics Committees for Performance Studies of *In Vitro* Diagnostic Medical Devices) Regulations 2022;

"official laboratory" means—

(a) the Public Analyst's Laboratory, Cork,
(b) the Public Analyst's Laboratory, Dublin,
(c) the Public Analyst's Laboratory, Galway,
(d) a laboratory designated by the Authority for the purposes of the EU Regulation, or
(e) a laboratory designated for the purposes of the EU Regulation in another member state;

"online interface" means any software, including a website, part of a website or an application, that is operated by or on behalf of an economic operator, and which serves to give end users access to the economic operator's products;

[4] OJ No. L 169, 25.6.2019, p. 1.

"person responsible for regulatory compliance" means any natural person who meets the requirements set out in Article 15(1) of the EU Regulation;

"premises" means any place (physical or virtual), ship or other vessel, aircraft, railway wagon or other vehicle or other mobile facility, and includes a container used to transport a device or other relevant thing, or any place used as part of the provision of a relevant service;

"prohibition order" means an order under Regulation 31;

"quarantine notice" means a notice under Regulation 29;

"record" includes, in addition to a record in writing—

(a) a disc, tape, sound-track or other thing in which information, sounds or signals are embodied so as to be capable, with or without the aid of some other instrument, of being reproduced in legible or audible form,
(b) a film, tape or other thing in which visual images are embodied so as to be capable, with or without the aid of some other instrument, of being reproduced in visual form,
(c) a photograph, and
(d) a digital record,

and any reference to a copy of a record includes—

(i) in the case of a record to which subparagraph (a) of this definition applies, a transcript of the sounds or signals embodied therein,
(ii) in the case of a record to which subparagraph (b) of this definition applies, a still reproduction of the images embodied therein, and
(iii) in the case of a record to which subparagraphs (a) and (b) of this definition apply, such a transcript together with such a still reproduction;

"Regulations of 2001" means the European Communities (*In Vitro* Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001);

"relevant service" means a diagnostic or therapeutic service offered by the means set out in Article 6 of the EU Regulation;

"relevant thing" means—

(a) a device,
(b) an in-house device,
(c) any article or substance used in the manufacture, processing, packaging, labelling, preparation, storage, distribution or advertising of a device or product referred to in subparagraph (a), or (b) or used in the context of a commercial activity described in Article 6(2) of the EU Regulation; or
(d) another product being used, or purporting to be used, for medical purpose;

"registered medical practitioner" has the same meaning as it has in the Medical Practitioners Act 2007;

"supply by mail order" means any supply made, after solicitation of custom by the supplier, or by another person in the chain of supply whether inside or outside of the State, without the supplier and the customer being simultaneously present and using a means of communication at a distance, whether written or electronic, to convey the custom solicitation and the order for supply.

(2) A word or expression which is used in these Regulations and which is also used in the EU Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the EU Regulation.

Additional functions of Authority

4. (1) In addition to the functions conferred on the Authority by Regulation 3 of the European Union (Medical Devices and *In Vitro* Diagnostic Medical Devices) Regulations 2017 (S.I. No. 547 of 2017), the functions of the State referred to in Article 3, second paragraph of Article 5(5), Articles 6(4), 15(1)(a), 15(6)(a), 19(3), 36(1), 38, 40(12), 43(2), 43(4), 47(3), 58(5)(a), 66, 67, 68(5), 69, 70, 71, 72, 73, 74, 76, 82(10), 84(2), 84(8), 85, 90, 91, 93, 95, 97(2), 100, 102(3), 102(4) and 103 of the EU Regulation shall be performed by the Authority.

(2) The Authority is designated as the market surveillance authority for *in vitro* diagnostic medical devices for the purposes of Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008[3] and the Market Surveillance Regulation.

Co-operation and exchange of information

5. (1) With the objective of performing its functions under these Regulations, the EU Regulation and the Market Surveillance Regulation, the Authority may cooperate, as appropriate, with Departments of State, agencies and bodies having, by law, responsibility for any matter relating to any aspect of those functions.

(2) For the purpose of performing its functions under these Regulations, the EU Regulation, and the Market Surveillance Regulation, the Authority may exchange information, including personal data, to the extent that it is necessary and appropriate, with relevant public authorities only for the purpose of performing their functions, including the following bodies:

(a) the Garda Síochána;
(b) the Revenue Commissioners;
(c) Sport Ireland;
(d) the Health Service Executive;
(e) the Pharmaceutical Society of Ireland;
(f) the Medical Council;
(g) the Dental Council;
(h) the Nursing and Midwifery Board;
(i) the Department of Health;
(j) the Department of Employment Affairs and Social Protection;
(k) the Environmental Protection Agency (EPA);

(l) the Competition and Consumer Protection Commission (CCPC);
(m) the Department of Enterprise, Trade and Employment;
(n) the Health Information and Quality Authority (HIQA);
(o) local authorities;
(p) competent authorities outside the State;
(q) European Union bodies; and
(r) the National Office.

PART 2

GENETIC TESTING

6. (1) Where a genetic test is used on an individual, in the context of healthcare as defined in point (a) of Article 3 of Directive 2011/24/EU of the European Parliament and of the Council[8] and for the medical purposes of diagnostics, improvement of treatment, predictive or prenatal testing, the individual being tested or, where applicable, his or her legally designated representative shall be provided with relevant information on the nature, the significance and the implications of the genetic test, as appropriate.

(2) In addition to the requirements set out in paragraph (1), where a genetic test that can provide information on the genetic predisposition for medical conditions or diseases which are generally considered to be untreatable according to the state of science and technology is used on an individual, he or she shall be appropriately counselled.

(3) Paragraph (2) shall not apply in cases where a diagnosis of a medical condition or a disease which the individual being tested is already known to have is confirmed by a genetic test or in cases where a companion diagnostic is used.

PART 3

PERFORMANCE STUDIES

Persons entitled to provide medical care to subjects

7. For the purposes of Article 58(5)(j) of the EU Regulation, the medical care provided to subjects is the responsibility of registered medical practitioners only.

Qualifications of investigators

8. (1) For the purposes of Article 58(7) of the EU Regulation –

(a) the investigator shall be a person of appropriate education, training and experience to assume responsibility for the proper conduct of the performance study, as determined by the sponsor,

[8] OJ L 88, 4.4.2011, p. 45.

and such determination shall be subject to review by the Authority and a National REC as part of its assessment of the performance study application;

(b) due consideration shall be given to ensuring the involvement of a registered medical practitioner or appointment of a registered medical practitioner to the role of investigator, where the study involves any direct patient contact.

Qualifications of persons carrying out prior interviews

9. For the purposes of Article 59(2)(c) of the EU Regulation, only registered medical practitioners are deemed to be appropriately qualified to carry out prior interviews with subjects, or, where the subject is not able to give informed consent, his or her legally designated representative for the purpose of obtaining his or her informed consent, as appropriate to the purpose of the performance study.

Submission of National REC opinion to the Authority

10. A sponsor of a performance study being conducted in the State shall submit to the Authority a copy of the opinion or opinions of a National REC in respect of the performance study—

(a) where it is available at the time of the application for an authorisation or notification, at that time, or

(b) as soon as a copy is available thereafter.

Starting of performance studies

11. A sponsor shall not start a performance study pursuant to Article 66(7)(a) of the EU Regulation, where the Authority has disagreed with the sponsor's position, as set out in the sponsor’s application to the Authority pursuant to Article 66(1) of the EU Regulation, that the performance study does not pose a major clinical risk to the subject of the study.

Notification of National Office of decisions on applications

12. The Authority shall inform the National Office of its decisions with respect to applications for authorisation of a performance study or a substantial modification of a performance study.

Appeals of decisions in relation to performance studies

13. (1) A sponsor may, within the time limit specified under paragraph (2), give notice to the

Authority of his, her or its wish to submit an appeal in respect of—

(a) a decision by the Authority, pursuant to Article 66(3) of the EU Regulation, to refuse authorisation for a performance study on the grounds that it does not fall within the scope of the EU Regulation or that the application is not complete,

(b) a decision by the Authority, pursuant to Article 67(4) of the EU Regulation, to refuse authorisation for a performance study on one of the grounds listed in that provision, or

(c) a decision by the Authority, pursuant to Article 71(3)(a) of the EU Regulation, to refuse authorisation for a substantial modification to a performance study.

(2) Any appeal shall be submitted to the Authority not later than 30 days after the date on which the sponsor was given notice of a decision specified in paragraph (1).

(3) The Authority shall publish guidelines setting out the procedures applicable to appeals under paragraph (1).

PART 4

OFFENCES

Offences by manufacturers

14. (1) Subject to Regulation 38, a manufacturer who—

(a) makes available on the market or puts into service a device which fails to comply with applicable common specifications pursuant to Article 9 of the EU Regulation,

(b) makes available on the market or puts into service a device which has not been designed or manufactured in accordance with the requirements of the EU Regulation,

(c) fails to establish, document, implement or maintain a system for risk management of devices as described in Section 3 of Annex I to the EU Regulation,

(d) makes available on the market or puts into service a device without conducting a performance evaluation in accordance with the requirements set out in Article 56 of, and Annex XIII to, the EU Regulation, including a PMPF,

(e) makes available on the market or puts into service a device, but fails to draw up or keep up to date technical documentation in accordance with Article 10(4) of the EU Regulation,

(f) fails to keep technical documentation, a declaration of conformity or a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 51 of the EU Regulation, available for the Authority in accordance with Article 10(7) of the EU Regulation,

(g) fails to establish or maintain a quality management system in accordance with Article 10(8) of the EU Regulation,

(h) makes available on the market or puts into service a device which is not accompanied by the information set out in Section 20 of Annex I to the EU Regulation in the manner required by Article 10(10) of the EU Regulation,

(i) places on the market or puts into service a device which it considers or has reason to believe is not in conformity with the EU Regulation and fails to take corrective action in accordance with Article 10(11) of the EU Regulation, and inform the distributor, and where applicable the authorised representative and importers, accordingly,

(j) places on the market or puts into service a device which presents a serious risk and which it considers or has reason to believe is not in conformity with the EU Regulation and fails to immediately inform the Authority or, where applicable, the notified body that issued a certificate for the device in accordance with Article 51 of the EU Regulation, of the non-compliance and of any corrective action taken,

(k) fails to comply with a request under Article 10(13) of the EU Regulation, to provide information and documentation necessary to demonstrate the conformity of a device, or a sample free of charge or grant access to a device,

(l) fails to comply with a request under Article 10(13) of the EU Regulation to cooperate with corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by a device which it has placed on the market or put into service,

(m) fails to include the information on the identity of any other legal or natural person who has designed or manufactured the device for the manufacturer as part of the information submitted in accordance with Article 27(1) of the EU Regulation,

(n) fails to put in place a necessary measure in accordance with Article 10(15) of the EU Regulation to provide sufficient financial coverage in respect of potential liability under Council Directive 85/374/EEC of 25 July 1985[9],

(o) fails to have available within his or her organisation, or permanently and continuously at his or her disposal, as required by Article 15 of the EU Regulation, at least one person responsible for regulatory compliance,

(p) has more than one person responsible for regulatory compliance and fails to stipulate in writing their respective areas of responsibility,

(q) places a device on the market in respect of which a person responsible for regulatory compliance has not been appointed in accordance with Article 15 of the EU Regulation,

(r) is not established in a member state and places on the market a device in respect of which an authorised representative has not been designated in accordance with Article 11 of the EU Regulation,

[9] OJ No. L 210, 7.8.1985, p. 29.

(s) changes its authorised representative without entering into an agreement in accordance with Article 12 of the EU Regulation,

(t) makes available on the market or puts into service a device, other than devices for performance study, that does not have affixed to it a CE marking in accordance with Article 18 of the EU Regulation,

(u) makes available on the market or puts into service a device, other than devices for performance study, but fails to draw up a declaration of conformity in relation thereto in accordance with Article 17 of the EU Regulation,

(v) places on the market a device, other than devices for performance study, without first assigning to it a UDI in accordance with Article 24(3) of the EU Regulation and transferring to the UDI database the information referred to in that provision,

(w) places a device on the market without placing UDI carriers on the label of the device and on all higher levels of packaging, in accordance with Article 24(4) of the EU Regulation,

(x) fails to keep up-to-date a list of all UDIs that he, she or it has assigned,

(y) places on the market a device, other than devices for performance study which has not been registered in the electronic system in accordance with Article 26 of the EU Regulation,

(z) places on the market a device, other than devices for performance study, without first assigning a basic UDI-DI to it in accordance with Article 26 of the EU Regulation,

(aa) places on the market a device, other than devices for performance study, without providing the basic UDI-DI to the UDI database together with the other core elements referred to in Part B of Annex VI related to that device,

(bb) places on the market a device, other than devices for performance study, without first entering or verifying in Eudamed the information referred to in Article 26(3) of the EU Regulation,

(cc) fails to update information entered in Eudamed pursuant to Article 26(3) of the EU Regulation,

(dd) in the case of class C and D devices, other than devices for performance studies, which it places on the market, fails to draw up a summary of safety and performance in accordance with Article 29 of the EU Regulation,

(ee) in the case of class C and D devices, other than devices for performance studies, which it places on the market, fails to include on the label or instructions for use information as to

where the summary of safety and clinical performance referred to in Article 29 of the EU Regulation is available,

(ff) fails to fulfil the post-market surveillance obligations in accordance with Chapter VII, Section 1 of the EU Regulation,

(gg) fails to comply with vigilance requirements in accordance with Chapter VII, Section 2 of the EU Regulation,

(hh) terminates its contract with a notified body and enters into a contract with a new notified body without executing an agreement in compliance with Article 53(1) of the EU Regulation, or

(ii) fails to update the performance evaluation of a device it has placed on the market or put into service, or the documentation relating thereto, in accordance with Article 56(6) of the EU Regulation,

(jj) fails to comply with the registration obligations laid out in Article 28 of the EU Regulation,

(kk) fails to comply with the general requirements regarding performance studies set out in Article 57(1) of the EU Regulation,

(ll) lodges an application in parallel with another notified body for the same conformity assessment procedure contrary to Article 49(1) of the EU Regulation, or

(mm) fails to make any applicable declarations in accordance with Article 49(3) of the EU Regulation,

is guilty of an offence.

(2) The offences listed in paragraph (1) also apply to an authorised representative where it has been validly designated, or is otherwise legally responsible for, the applicable manufacturer's obligation under the EU Regulation, in accordance with Article 11 thereof.

(3) Subject to paragraphs (4) and (5), the offences listed in paragraph (1) also apply to a distributor, importer or other natural or legal person where he, she or it—

(a) makes available on the market a device under his, her or its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in the EU Regulation,

(b) changes the intended purpose of a device already placed on the market or put into service, or

(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements of the EU Regulation may be affected,

in which circumstances, such person shall be regarded as the manufacturer for the purpose of the said offences.

(4) Paragraph (3)(a) shall not apply to any person who, while not considered a manufacturer, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.

(5) For the purposes of paragraph (3)(c), the actions listed in Article 16(2) of the EU Regulation shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements.

Offences by authorised representatives

15. Subject to Regulation 38, an authorised representative who—

(a) fails to provide to the Authority a copy of a mandate agreed between he, she or it and the manufacturer which is in accordance with Article 11 of the EU Regulation,

(b) fails to verify that the EU declaration of conformity and technical documentation have been drawn up in respect of a device in respect of which he, she or it has been designated,

(c) if applicable, fails to verify that an appropriate conformity assessment has been carried out by the manufacturer of a device in respect of which he, she or it has been designated,

(d) fails to keep available, at the disposal of the Authority for the period referred to in Article 10(7) of the EU Regulation, a copy of—

(i) the technical documentation,

(ii) the EU declaration of conformity, or

(iii) any relevant certificate issued in accordance with Article 51 of the EU Regulation,

in relation to a device in respect of which he, she or it has been designated,

(e) fails to comply with the registration obligations laid down in Article 28 of the EU Regulation in relation to a device in respect of which he, she or it has been designated,

(f) fails to verify that the manufacturer of a device in respect of which he, she or it has been designated has complied with the registration obligations laid down in Articles 26 of the EU Regulation,

(g) fails to provide to the Authority, on request, information or documentation necessary to demonstrate the conformity of a device in respect of which he, she or it has been designated,

(h) fails to forward to the manufacturer of a device in respect of which he, she or it has been designated any request from the Authority for samples or access to the device, or fails to verify that the Authority receives such samples or is given such access,

(i) fails to cooperate with the Authority on any preventive or corrective action taken to eliminate or mitigate the risks posed by a device in respect of which he, she or it has been designated,

(j) fails to immediately inform the manufacturer of a device in respect of which he, she or it has been designated about a complaint or report from a healthcare professional, patient or user about a suspected incident related to the device,

(k) fails to terminate the mandate if the manufacturer acts contrary to its obligations under the EU Regulation,

(l) fails to immediately inform the Authority or any relevant notified body of the termination of its mandate, where required under Article 11(6) of the EU Regulation, or

(m) fails to have permanently and continuously at his or her disposal at least one person responsible for regulatory compliance, in accordance with Article 15(6) of the EU Regulation,

is guilty of an offence.

Offences by distributors

16. Subject to Regulation 38, a distributor who—

(a) makes available on the market a device, which has not been CE marked in accordance with Article 18 of the EU Regulation,

(b) makes available on the market a device which does not have an EU declaration of conformity in accordance with Article 17 of the EU Regulation,

(c) makes available on the market a device which is not accompanied by the information to be supplied by the manufacturer in accordance with Article 10(10) of the EU Regulation,

(d) makes available on the market an imported device in respect of which the importer has not complied with the requirements in Article 13(3) of the EU Regulation,

(e) makes available on the market a device, which has not been assigned a UDI by the manufacturer,

(f) makes available on the market a device which it considers, or has reason to believe, is not in conformity with the EU Regulation,

(g) considers or has reason to believe that a device which he, she or it has made available on the market is not in conformity with the EU Regulation and fails to inform the manufacturer, and where applicable the manufacturer's authorised representative and the importer, of such non-conformity in accordance with Article 14(2) of the EU Regulation,

(h) considers or has reason to believe that a device presents a serious risk or is a falsified device and fails to inform the relevant competent authority of such risk in accordance with Regulation 14(2) of the EU Regulation,

(i) stores or transports a device without complying with the conditions set by the manufacturer,

(j) considers or has reason to believe that a device which he, she or it has made available on the market is not in conformity with the EU Regulation and fails to immediately inform the manufacturer

and where applicable, the manufacturer's authorised representative and the importer, or fails to take corrective measures in accordance with Article 14(4) of the EU Regulation,

(k) considers or has reason to believe that a device which he, she or it has made available on the market is not in conformity with the EU Regulation and presents a serious risk and fails inform the relevant competent authority of the non-compliance and of any corrective action, taken in accordance with Article 14(4) of the EU Regulation,

(l) receives a complaint or report about a suspected incident related to a device it has made available, but fails to comply with Regulation 14(5) of the EU Regulation,

(m) fails to provide the Authority with information, documentation, cooperation or a sample, or access to, a device following a request by the Authority under Article 14(6) of the EU Regulation, or

(n) carries out any of the activities referred to in Article 16(2) of the EU Regulation and fails to—

(i) provide the information required by Article 16(3) of the EU Regulation with the device concerned,

(ii) have in place a quality management system in accordance with the requirements of Article 16(3) of the EU Regulation, or

(iii) provide the manufacturer or the Authority with information or documentation in accordance with Article 16(4) of the EU Regulation,

is guilty of an offence.

Offences by importers

17. Subject to Regulation 38, an importer who—

(a) places on the market a device which has not been CE marked in accordance with Article 18 of the EU Regulation,

(b) places on the market a device which does not have an EU declaration of conformity in accordance with Article 17 of the EU Regulation,

(c) places on the market a device which the importer considers, or has reason to believe, is not in conformity with the requirements of the EU Regulations,

(d) places on the market a device in respect of which the manufacturer has not been identified,

(e) places on the market a device in respect of which an authorised representative has not been designated in accordance with Article 11 of the EU Regulation,

(f) is established in the State and fails to inform the Authority that he, she or it considers, or has reason to believe, that a device it intended to place on the market presents a serious risk or is a falsified device,

(g) places on the market a device which is not labelled in accordance with the EU Regulation or is not accompanied by the required instructions for use,

(h) places on the market a device, which has not been assigned a UDI by the manufacturer in accordance with Article 24 of the EU Regulation, where applicable,

(i) places on the market a device without complying with the information and labelling requirements in Article 13(3) of the EU Regulation,

(j) places on the market a device, which has not been registered in the electronic system in accordance with Article 26 of the EU Regulation,

(k) within 2 weeks of placing on the market a device, which has already been registered on the electronic system referred to in Article 27 of the EU Regulation, fails to—

(i) verify that the manufacturer or authorised representative of the device has provided the information referred to in Section 1 of Part A of Annex VI to the EU Regulation to, or

(ii) add his, her or its details to the relevant entry or entries in, the said electronic system, or

(iii) where applicable, inform the relevant authorised representative or manufacturer if the information referred to in Article 27(1) is not included or is incorrect,

(l) stores or transports a device under its responsibility in a manner contrary to the requirements of Article 13(5) of the EU Regulation,

(m) fails to keep a register, or provide information, in accordance with Article 13(6) of the EU Regulation,

(n) fails to inform the manufacturer or authorised representative, in accordance with Article 13(7) of the EU Regulation, where he, she or it considers or has reason to believe that a device which the importer has placed on the market is not in conformity with the EU Regulation,

(o) fails to cooperate in corrective measures required under Article 13(7) of the EU Regulation,

(p) fails to inform the relevant competent authorities or notified body, in accordance with Article 13(2) or 13(7) of the EU Regulation, where he, she or it considers or has reason to believe that a device it has placed on the market presents a serious risk,

(q) fails to forward to the manufacturer or its authorised representative information in relation to complaints or reports of suspected incidents related to a device the importer has placed on the market, in accordance with Regulation 13(8) of the EU Regulation,

(r) fails to keep a copy of the EU declaration of conformity or any relevant certificate issued in accordance with Article 51, in accordance with Article 13(9) of the EU Regulation,

(s) fails to provide the Authority with cooperation, or samples or access to a device, upon request by the Authority under Article 13(10) of the EU Regulation, or

(t) carries out any of the activities referred to in Article 16(2) of the EU Regulation and fails to—

(i) provide the information required by Article 16(3) of the EU Regulation with the device concerned,

(ii) have in place a quality management system in accordance with the requirements of Article 16(3) of the EU Regulation, or

(iii) provide the manufacturer or the Authority with information or documentation in accordance with Article 16(4) of the EU Regulation,

is guilty of an offence.

Offences – economic operators

18. Subject to Regulation 38, an economic operator who—

(a) fails to identify any of the persons or institutions referred to in Article 22(2) of the EU Regulation during the period referred to in Article 10(7) of the EU Regulation,

(b) fails to store and keep the UDI of a device referred to in Article 24(8) of the EU Regulation which he, she or it has supplied or with which he, she or it has been supplied,

(c) fails to update the data in relation to a device for which it is responsible in the electronic system referred to in Article 27 of the EU Regulation within one week of a change occurring in relation to information referred to in Article 28(4) of the EU Regulation,

(d) fails, within one year of submission or every second year thereafter, to confirm the accuracy of the information in the electronic system in accordance with Article 28(5) of the EU Regulation in relation to a device for which it is responsible,

(e) fails to make documentation or information available to the Authority in accordance with a request under Article 88(3)(a) of the EU Regulation,

(f) fails to provide a sample of, or access free of charge to, a device in accordance with a request under Article 88(3)(a) of the EU Regulation,

(g) fails to allow the Authority access to his or her premises for the purposes of an inspection under Article 88(3)(b) of the EU Regulation,

(h) fails to cooperate with the Authority in relation to the evaluation, under Article 89 of the EU Regulation of a device for which it is responsible,

(i) fails to take corrective action required by the Authority under Article 90 of the EU Regulation,

(j) fails to bring to an end a non-compliance with the EU Regulation, in accordance with a request by the Authority under Article 92 of the EU Regulation,

is guilty of an offence.

Offences by notified bodies

19. Subject to Regulation 38, a notified body which—

(a) fails to comply with the requirements of Article 32(1) of the EU Regulation,

(b) fails, where requested, to make available and submit relevant documentation to the Authority in accordance with Article 32(2) of the EU Regulation,

(c) delegates specific tasks connected with conformity assessment to a subcontractor or subsidiary which does not meet the applicable requirements set out in Annex VII to the EU Regulation,

(d) fails to inform the Authority, pursuant to Article 33(1) of the EU Regulation, that a subcontractor or subsidiary is carrying out specific tasks connected with conformity assessment on its behalf,

(e) fails to make publicly available a list of its subsidiaries in accordance with Article 33(3) of the EU Regulation,

(f) fails to inform an applicant for conformity assessment, pursuant to Article 33(4) of the EU Regulation, that conformity assessment activities will be carried out by a subcontractor or subsidiary,

(g) fails to keep at the disposal of the Authority, pursuant to Article 33(5) of the EU Regulation, all relevant documents concerning the verification of the qualifications of a subcontractor or subsidiary carrying out tasks connected with conformity assessment on its behalf and the tasks carried out by the subcontractor or subsidiary,

(h) fails to inform the Authority, pursuant to Article 34(3) of the EU Regulation, of a relevant change in the documentation referred to in Article 34(2) of the EU Regulation,

(i) fails to inform the Authority within 15 days, pursuant to Article 40(1) of the EU Regulation, of a relevant change which may affect its compliance with the requirements set out in Annex VII to the EU Regulation or its ability to conduct the conformity

assessment activities relating to the devices for which it has been designated,

(j) fails to comply with a request by the Authority to supply information and documents pursuant to Article 40(2) of the EU Regulation,

(k) fails to comply with a request by the Commission or the authority of a member state other than the State, pursuant to Article 40(3) of the EU Regulation, within 15 days of such request,

(l) fails to inform the Authority, in accordance with Article 42(3) of the EU Regulation, that it intends to cease conformity assessment activities,

(m) fails to inform a manufacturer concerned that the notified body's designation has been suspended, restricted or fully or partially withdrawn pursuant to Article 42(5) of the EU Regulation,

(n) fails to suspend or withdraw an unduly issued certificate in accordance with a request by the Authority under Article 42(7) of the EU Regulation,

(o) fails to make publicly available, in accordance with Article 46 of the EU Regulation, a list of its standard fees for the conformity assessment activities that it carries out,

(p) fails to request one of the EU reference laboratories to verify the performance claimed by the manufacturer and the compliance of the device with the applicable CS, in accordance with Article 48 (5) of the EU Regulation,

(q) fails to consult the relevant experts referred to in Article 106 of Regulation (EU) 2017/745 on the performance evaluation report of the manufacturer in accordance with Article 48(6), as applicable,

(r) with respect to companion diagnostics, fails to consult the Authority or the EMA, as applicable, in accordance with the procedure set out in Section 5.2 of Annex IX or point (k) of Section 3 of Annex X of the EU Regulation,

(s) fails to notify the Authority of certificates it has granted for class D devices in accordance with Article 50(1) of the EU Regulation, as applicable,

(t) fails to take appropriate action to address the failure of a manufacturer to meet the requirements of the EU Regulation, in accordance with Article 51(4) of the EU Regulation,

(u) fails to notify the competent authorities, through the electronic system referred to in Article 52 of the EU Regulation of a certificate it has granted to a device in respect of which it has performed a conformity assessment, in accordance with Article 50(1) of the EU Regulation,

(v) enters into a contract with a manufacturer which is changing notified bodies without executing an agreement in compliance with Article 53(1) of the EU Regulation,

(w) fails to withdraw, in accordance with Article 53(2) of the EU Regulation, a certificate it issued which has become invalid in

the context of the termination of the contract with the manufacturer, or

(x) fails to enter in the electronic system referred to in Article 52 of the EU Regulation the information referred to in Article 51(5) of the EU Regulation regarding a certificate it has issued,

is guilty of an offence.

Offences by health institutions

20. Subject to Regulation 38, a health institution which—

(a) manufactures and uses an in-house device which is not in compliance with the relevant general safety and performance requirements set out in Annex I to the EU Regulation,

(b) fails to comply with a condition in Article 5(5) of the EU Regulation in respect of an in-house device which it manufactures and uses,

is guilty of an offence.

Offences by sponsors

21. (1) Subject to Regulation 38, a sponsor who is responsible for a performance study to be, or being, conducted in the State and who fails to ensure that the performance study is designed and conducted, in accordance with Article 57 of the EU Regulation, is guilty of an offence.

(2) Subject to paragraphs 4 to 7 and Regulation 38, a sponsor who, in respect of a performance study that meets the criteria set out in Article 58 of the EU Regulation, or falls under Article 70(2) of the EU Regulation, which is to be, or being, conducted in the State, for which the sponsor is responsible—

(a) fails to ensure that the performance study is designed, authorised, conducted, recorded and reported in accordance with Article 58 of the EU Regulation, where applicable,

(b) fails to notify the Authority of performance studies involving companion diagnostics using only left-over samples,

(c) fails to ensure that all of the conditions listed in Article 58(5) of the EU Regulation are met, as applicable,

(d) fails to ensure that all of the conditions listed in Article 60(1) of the EU Regulation are met, as applicable,

(e) fails to ensure that all of the conditions listed in Article 61(1) of the EU Regulation are met, as applicable,

(f) fails to ensure that all of the conditions listed in Article 62(1) of the EU Regulation are met, as applicable,

(g) fails to submit to the Authority a copy of an opinion of a National REC in respect of a performance study in accordance with Regulation 10,

(h) starts the performance study otherwise than in accordance with Article 66(7) of the EU Regulation and Regulation 11,

(i) fails to ensure that the performance study is conducted in accordance with the approved performance study plan and Article 68 of the EU Regulation,

(j) fails to ensure adequate monitoring of the conduct of the performance study in accordance with Article 68(2) of the EU Regulation,
(k) fails to establish a procedure in accordance with Article 68(6),
(l) fails to inform the Authority of the information in relation to a substantial modification in accordance with the requirements of Article 71(1),
(m) implements the modifications referred to in Article 71(1), other than in accordance with the requirements of paragraph (3) thereof,
(n) fails to inform the Authority of the temporary halting or early termination of the performance study in accordance with Article 73(1) of the EU Regulation,
(o) fails to notify the Authority of the end of the performance study in accordance with Article 73(3) or (4) of the EU Regulation,
(p) fails to submit a performance study report in accordance with Article 73(5) of the EU Regulation,
(q) fails to record information in accordance with Article 76(1) of the EU Regulation, or
(r) fails to report to the Authority in accordance with Article 76(2), (3) or (4) of the EU Regulation, as applicable,

is guilty of an offence.

(3) A sponsor of a performance study in the State who is not established in the European Economic Area is guilty of an offence where he, she or it fails to ensure that a natural or legal person is established in the European Economic Area as its legal representative ("legal representative") in accordance with Article 58(4) of the EU Regulation,

(4) Where a legal representative has been appointed in accordance with Article 58(4), the offences listed in paragraph (1) apply to the legal representative in place of the sponsor.

(5) A sponsor or legal representative, as the case may be, is not guilty of an offence under paragraphs (1) or (2) by reason of the failure to ensure compliance with Article 58(5)(f), 60(1)(a) or (b), or 61(a) or (b), of the EU Regulation where an emergency situation derogation under Article 64(1) of the EU Regulation applies and the relevant requirements of Article 64(2) and (3) of the EU Regulation are met.

(6) In the case of a performance study coming within the scope of Article 70(1) of the EU Regulation ("PMPF investigation"), which is considered notifiable to the Authority, the offences in paragraphs (1) and (2) shall not apply, other than those at paragraph (2), subparagraphs (l), (m), (n), (o) and (p) thereof, and the sponsor or legal representative of the performance study is, in addition, guilty of an offence where he, she or it—

(a) fails to notify the Authority in accordance with Article 70(1) of the EU Regulation including the relevant documentation as per Article 70(1),
(b) fails to ensure that the conditions listed in Article 58(5)(b) to (l) and (p) of the EU Regulation are met,

(c) fails to ensure that the relevant provisions of Annexes XIII and XIV are met, or

(d) fails to ensure that the provisions on vigilance laid down in Articles 82 to 85 of the EU Regulation are complied with.

(7) Notwithstanding paragraph (5), the offences in paragraph (1)(q) and (r) shall apply to the sponsor or legal representative of a PMPF investigation where a causal relationship between the serious adverse event and the preceding performance study has been established.

Offences - general

22. Subject to Regulation 38, a person who—

(a) makes available on the market or puts into service a device which fails to comply with a general safety and performance requirement under Annex I to the EU Regulation which applies to it taking into account its intended purpose,

(b) offers by means of information society services, to a natural or legal person established in a member state, a device which is not in compliance with the EU Regulation,

(c) offers in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services or by other means of communication, directly or through intermediaries, to a natural or legal person established in a member state, a device which is not in compliance with the EU Regulation,

(d) offers a device by means of information society services in accordance with Article 6(1) of the EU Regulation, or provides a service in accordance with Article 6(2) of the EU Regulation, and fails to make available to the Authority on request a copy of the EU declaration of conformity of the device,

(e) fails to comply with a request by the Authority pursuant to Article 6(4) of the EU Regulation to cease providing information society services,

(f) in the labelling, instructions for use, making available, putting into service or advertising of a device, uses text, names, trademarks, pictures or figurative or other signs that may mislead the user or the patient contrary to Article 7 of the EU Regulation,

(g) makes available on the market an item, specifically intended to replace an identical or similar integral part or component of a device in the circumstances referred to in Article 20(1) of the EU Regulation, which adversely affects the safety and performance of the device,

(h) having made available on the market an item referred to in Article 20(1) of the EU Regulation, fails to keep supporting

evidence of compliance with that provision available for the Authority,

(i) places on the market, or puts into service, a device that has not been the subject of a conformity assessment in accordance with Article 48 of the EU Regulation or which has not been subject of a derogation granted under Article 54 of the EU Regulation,

(j) fails to comply with a request, notice or order made under these Regulations,

(k) in purported compliance with a request, notice or order under these Regulations gives information to the Authority or an authorised officer that he, she or it knows to be false or misleading in any material respect,

(l) obstructs or interferes with the Authority, an authorised officer, a member of An Garda Síochána or a person with expertise relating to any relevant thing or relevant service, in the course of performing a function conferred on him, her or it by these Regulations,

(m) falsely represents himself or herself to be an authorised officer under these Regulations,

(n) impedes the performance by a person referred to in paragraph (l) of such function, or fails or refuses to comply with a request or requirement of, or to answer a question asked by such person,

(o) discloses any confidential information to which he, she or it has access by virtue of these Regulations, otherwise than in accordance with these Regulations,

(p) fails to take reasonable measures to guarantee confidentiality with regard to forwarding any documentation required under these Regulations,

(q) makes a false document or possesses or uses a document knowing it to be false or purporting to be issued, granted, given or required under this Regulation or the EU Regulation ("a false document"),

(r) alters with intent to defraud or deceive, or uses knowing it to be so altered, a document issued, granted, given or required under these Regulations or the EU Regulation ("an altered document"),

(s) without lawful authority, has in his, her or its possession a false document or an altered document,

(t) tampers with any device or other relevant thing, or any material or accessory designated to be used as part of or with a device or other relevant thing,

(u) tampers or interferes with any sample taken under Regulation 26(3)(i) or (j),

(v) being a supplier of a device, or a subcontractor of a manufacturer, fails to allow the Authority access to his, her or its premises for the purposes of an inspection under Article 88(3)(b) of the EU Regulation, or

(w) being a professional user of a device, fails to allow the Authority access to his, her or its facilities for the purpose of a necessary inspection under Article 88(3)(b) of the EU Regulation,

is guilty of an offence.

Provisions related to offences

23. (1) For the purpose of these Regulations, every contravention of a provision of these Regulations shall be deemed a separate contravention and every contravention of a paragraph or a subparagraph of such provision shall also be deemed to be a separate contravention and shall carry the same penalty as for a single contravention of any such provision.

(2) Where a person is convicted of an offence under these Regulations, the court shall, unless it is satisfied that there are special and substantial reasons for not doing so, order the person to pay to the Authority the costs and expenses, measured by the court, incurred by the Authority, in relation to the investigation, detection and prosecution of the offence, including costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisors engaged by the Authority.

(3) On conviction for an offence under these Regulations, the court may, in addition to any other penalty or cost—

(a) order any relevant thing or any vehicle, vessel or container to which the offence relates to be forfeited to the Authority for destruction or disposal as the Authority thinks fit,

(b) order the cessation of any relevant service, and

(c) upon application made to it by or on behalf of the Authority, order the person convicted of the offence to pay to the Authority all or part of the costs of the destruction or disposal of such relevant thing or any vehicle, vessel or container, subject to such conditions, if any, as specified in the order.

(4) An order for costs and expenses under paragraph (2) or (3) is in addition to, and not instead of, any fine or penalty the court may impose.

(5) In any proceedings for an offence under these Regulations, where no conviction is recorded, the court may, upon application made to it by or on behalf of the Authority, order any relevant thing to which the offence relates to be forfeited to the Authority for destruction or disposal.

Proceedings

24. (1) Proceedings in relation to a summary offence under these Regulations may be brought and prosecuted by the Authority.

(2) In proceedings for an offence under these Regulations, a certificate or report signed by an approved examiner stating the results of any test, examination or analysis of a sample shall, with regard to that sample, be evidence of the matters stated in the certificate or report unless the contrary is proved.

(3) In proceeding for an offence under these Regulations, a relevant thing or relevant service, or package containing a relevant thing, that purports to bear the name of the manufacturer or importer of that thing, or of the person who made that thing available on the market, shall, unless the contrary is proved, be evidence that the relevant thing or relevant service was manufactured or imported, offered by means of information society services or made available on the market, as the case may be, by the person so named.

PART 5

COMPLIANCE AND ENFORCEMENT

Enforcement generally

25. (1) Save for Part 2, these Regulations, and the provisions of the EU Regulation to which they refer, shall be enforced by the Authority.

(2) In carrying out its compliance and enforcement role under the EU Regulation and these Regulations, the Authority shall adhere to the principle of good administrative practice, as provided for in Article 94 of the EU Regulation.

Authorised officers

26. (1) For the purposes of ensuring compliance with the EU Regulation and these Regulations, the chief executive of the Authority—

(a) may appoint such and so many persons as he or she thinks fit to be authorised officers for the purpose of these Regulations, and

(b) shall furnish each authorised officer appointed by him or her with a warrant of the authorised officer's appointment.

(2) An authorised officer, other than an authorised officer who is an officer of Customs and Excise, shall, when performing a function imposed under these Regulations on an authorised officer, produce his or her warrant for inspection if requested to do so by a person affected by the performance of that function.

(3) For the purposes of ensuring compliance with the EU Regulation or the Market Surveillance Regulation, an authorised officer may—

(a) subject to paragraph (5), enter (if necessary by the use of reasonable force), at all reasonable times, any premises at which he or she has reasonable grounds for believing that—

(i) any trade, business or activity connected with the manufacture, processing, sterilisation, disposal, export, import, distribution, sale, supply, storage, packaging, labelling, preparation, professional use, conformity assessment, or advertising of any relevant thing or relevant

service or the processing of financial transactions in relation to the relevant thing or relevant service is or has been carried on, or

(ii) books, records or other documents (including documents stored in non-legible form) relating to such trade, business or activity or the processing of financial transactions in relation to the relevant thing or relevant service are kept,

(b) at such premises inspect and take copies of any books, records, other documents (including documents stored in non-legible form) or extracts therefrom, which he or she finds in the course of his or her inspection,

(c) remove any such books, records or other documents from such premises and detain them for such period as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,

(d) carry out, or have carried out, such tests, examinations, analyses, inspections and checks of—

(i) the premises,

(ii) any relevant thing at the premises, or

(iii) any equipment, machinery or plant at the premises,

as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,

(e) require any person at the premises, the owner or person in charge of the premises or any person employed there to give to him or her such assistance and information and to produce to him or her such books, records or other documents (and in the case of documents or records stored in non-legible form, produce to him or her a legible reproduction thereof) that are in that person's power or procurement, as he or she may reasonably require for the purposes of his or her functions under these Regulations,

(f) purchase or take without payment a sample of any relevant thing found at the premises for the purposes of any test, examination or analysis,

(g) secure and detain for later inspection any premises or part of any premises in which a relevant thing is found or ordinarily kept, or books, records or other documents are found or ordinarily kept, for such period as may reasonably be necessary for the purposes of his or her functions under these Regulations,

(h) without payment, take possession of and remove from the premises for any test, examination or analysis any relevant thing found there, and detain it for such period as he or she considers reasonably necessary for the purposes of his or her functions under these Regulations,

(i) without payment, take samples of any relevant thing detained pursuant to subparagraph (j), for the purposes of any test, examination, or analysis,

(j) where the taking of samples of any relevant thing pursuant to subparagraph (f) or (i) is, for whatever reason, not practicable,

purchase or take without payment the relevant thing concerned for the purposes of any test, examination or analysis, or carry out testing, examination or analysis of the relevant thing at the premises,

(k) stop any person, vehicle, vessel or container at the premises,

(l) board and inspect any such vehicle, vessel or container,

(m) require the name and address of any person on the premises,

(n) make a record whether in writing, by photography or otherwise,

(o) inspect and copy or extract information from any data within the meaning of the Data Protection Acts 1988 to 2018,

(p) require a person, having authority to do so, to break open any container, receptacle or package, or to open any vending machine, or to permit him or her to do so, as he or she may reasonably require for the purposes of his or her functions under these Regulations,

(q) require a person, who makes available facilities such as post office boxes, telecommunications, financial payment services, electronic mail addresses or other like facilities, to give him or her such assistance and information as he or she may reasonably require for the purposes of his or her functions under these Regulations in any case where the officer has reasonable grounds for believing that any relevant thing or relevant service is being supplied by information society services or mail order, or in contravention of any provision of these Regulations or the EU Regulation relating to any trade, business or activity referred to in subparagraph (a)(i), or books, records or documents referred to in subparagraph (a)(ii), or

(r) where no other effective means are available to eliminate a serious risk—

(i) require the removal of content referring to devices and other relevant things or relevant services from an online interface or require the explicit display of a warning to end users when they access an online interface, or

(ii) where a request under clause (i) has not been complied with, require information society service providers to restrict access to the online interface, including by requesting a relevant third party to implement such measures.

(4) When performing a function under these Regulations, an authorised officer may, subject to any warrant under paragraph (6), be accompanied by such number of—

(a) other authorised officers,

(b) members of An Garda Síochána, or

(c) persons with expertise relating to any relevant thing or relevant service,

as he or she considers appropriate in the circumstances of the case.

(5) An authorised officer shall not enter a dwelling, other than—

(a) with the consent of the occupier, or

(b) in accordance with a warrant issued under paragraph (6).

(6) Upon the application of an authorised officer, a judge of the District Court, if satisfied

that there are reasonable grounds for believing that—

(a) a relevant thing is to be found in any dwelling, or is being or has been subjected to any process or stored in any dwelling,

(b) a dwelling is occupied in whole or in part by an undertaking engaged in any trade, business or activity referred to in paragraph (3)(a)(i), or

(c) books, records or other documents (including documents stored in non-legible form) referred to in paragraph (3)(a)(ii) are being stored or kept in any dwelling,

may issue a warrant authorising a named authorised officer accompanied by such other authorised officers, members of An Garda Síochána, or persons with expertise relating to any relevant thing or relevant service, as may be necessary, at any time or times, within one month of the date of issue of the warrant, to enter the dwelling and perform any of the functions of an authorised officer under paragraph (3)(b) to (r).

(7) Where an authorised officer, upon reasonable grounds, believes that a person has committed an offence under these Regulations, he or she may require that person to provide him or her with his or her name, date of birth, and the address at which he or she ordinarily resides, and to produce corroborative evidence of same.

(8) Where an authorised officer has reasonable cause to suspect that—

(a) an offence is being or has been committed under these Regulations, or

(b) evidence of an offence or contravention may be, is or has been on or in any premises,

the authorised officer may, in addition to the powers exercisable by him or her under paragraph (3)—

(i) search a person, where the authorised officer considers it necessary,

(ii) seize and detain a vessel, vehicle, container, equipment, machinery or relevant thing,

(iii) require the cessation of a relevant service,

(iv) dispose of a relevant thing, or require the owner or person in charge of a relevant thing or relevant service or in possession of a relevant thing to deal with or dispose of it (or any other thing used in connection with the relevant thing or relevant service, or that may have been in contact with, the relevant thing) in a manner that the authorised officer thinks fit.

(9) An authorised officer may dispose of, or cause to be disposed, a relevant thing, or a sample of a relevant thing, taken under this Regulation, in such manner and at such place as the authorised officer considers appropriate in the circumstances of the case.

(10) The costs (including ancillary costs) of any seizure, detention or disposal carried out by the Authority under paragraph (8) or (9) shall be recoverable as a simple contract debt in any court of competent jurisdiction from the relevant manufacturer, distributor, importer or other person responsible for the item seized, detained or disposed of.

(11) A statement or admission made by a person pursuant to a requirement under paragraph (3) shall not be admissible as evidence in proceedings brought against that person for an offence (other than an offence under these Regulations for failing to give information or giving false information).

(12) Nothing in this Regulation shall be taken to compel the production by any person of a document which he or she would be exempt from producing in proceedings in a court on the ground of legal professional privilege.

Taking of samples

27. (1) Subject to paragraph (3), where an authorised officer purchases or takes without payment a sample of a relevant thing pursuant to Regulation 26(3)(i) he or she may, where practicable—

(a) take multiple samples,
(b) place each sample into separate containers, and
(c) forthwith seal and mark each such container in such a manner as to identify it as part of the sample taken by the authorised officer.

(2) Where the authorised officer has, sealed and marked a sample of a relevant thing in accordance with paragraph (1), he or she shall—

(a) offer one of the sealed containers to the owner or the person for the time being in charge or possession of the relevant thing from which the sample concerned was taken,
(b) retain one of the sealed containers, and
(c) forward, or cause to be forwarded, one of the sealed containers for test, examination or analysis of the sample concerned by an approved examiner or where appropriate for examination by the Authority.

(3) Where a relevant thing is contained in a container and, for whatever reason, it is not practicable to take multiple samples, an authorised officer, who wishes to take samples of such relevant things for the purposes of any tests, examination or analysis may take possession of 3 such containers belonging to the same batch or lot, and each such container shall be deemed to be part of a sample for the purposes of paragraph (1), and the provision of paragraphs (1) and (2) shall apply thereto accordingly.

(4) Where an authorised officer purchases or takes without payment a relevant thing pursuant to Regulation 26(3)(j) he or she may, where practicable—

(a) place the relevant thing in a container,

(b) forthwith seal and mark the container in such a manner as to identify it as a relevant thing taken pursuant to that subparagraph, and

(c) forward, or cause to be forwarded, the sealed container for test, examination or analysis of the relevant thing by an approved examiner

Production order

28. (1) For the purpose of investigating compliance with the EU Regulation and these Regulations, an authorised officer may apply to a judge of the District Court for an order under this Regulation ("production order") in relation to making available any particular material or material of a particular description.

(2) On an application under paragraph (1), the judge, if satisfied—

(a) that there are reasonable grounds for suspecting that the person on whom the order is to be served has the material concerned in his or her possession or has access to such material, and

(b) that the material concerned is required for the purpose of such investigation,

may order that the person shall—

(i) produce the material to the authorised officer so that he or she may take it away, or

(ii) give the authorised officer access to it within a period to be specified in the order.

(3) The period to be so specified shall be one week, unless it appears to the judge that another period would be appropriate in the particular circumstances of the case.

(4) An order under this Regulation in relation to material in any place may, on the application of the authorised officer concerned, require any person who appears to the judge to be entitled to grant entry to the place to allow the authorised officer to enter it to obtain access to the material.

(5) Where a person required under paragraph (4) to allow an authorised officer to enter a place does not allow the authorised officer to do so, the person shall be treated as if he or she is in breach of a warrant issued under Regulation 26(6) authorising him or her to search the place and any person found there.

(6) Where material to which a production order relates consists of information stored electronically, the order shall have effect as an order to produce the material, or to give access to it, in a form in which it is visible and legible and in which it can be taken away.

(7) A production order —

(a) in so far as it may empower an authorised officer to take away a document or to be given access to it, shall authorise him or her to make a copy of it and to take the copy away,

(b) shall not confer any right to production of, or access to, any material subject to legal privilege, and

(c) shall have effect notwithstanding any other obligation as to secrecy or other restriction on disclosure of information imposed by statute or otherwise.

(8) Any material taken away by an authorised officer under this Regulation may be retained by him or her for use as evidence in any proceedings.

(9) A judge of the District Court may vary or discharge an order under this Regulation on the application of any person to whom an order under this Regulation relates or an authorised officer.

Quarantine notice

29. (1) Where an authorised officer, other than an authorised officer who is an officer of Customs and Excise, is of the opinion that—

(a) there is a potential non-compliance with a requirement of the EU Regulation or these Regulations in relation to a device or other relevant thing or relevant service, or

(b) a device or other relevant thing or relevant service has the potential to pose a serious risk to human health,

the authorised officer may, with the approval of the chief executive of the Authority, or another officer of the Authority designated by the chief executive of the Authority for that purpose, serve, or arrange to have served, on the manufacturer, authorised representative, distributor, health institution, economic operator, notified body or other person(s) concerned a notice ("quarantine notice") in accordance with paragraph (2).

(2) A quarantine notice shall—

(a) be signed by the authorised officer issuing it, or the officer consulted in accordance with paragraph (1),

(b) state the reason why quarantine is being applied or provide a justification for the quarantine action,

(c) specify—

(i) the provision or provisions of the EU Regulation or these Regulations with which there is non-compliance and the matters giving rise to the non-compliance, or

(ii) the serious risk to human health posed by the device or relevant thing or relevant service, and

(iii) direct the person on whom the quarantine notice is served to ensure that the device or relevant thing or relevant service is not to be placed on the market, made available on the market, put into service or offered by means of information society services until all the necessary conditions for the device, relevant thing or relevant service to be compliant have been met or the device, relevant thing or relevant service no longer poses a serious risk to human health, as appropriate.

(3) The approval referred to in paragraph (1) may be given orally or in writing and if given orally shall be recorded in writing as soon as practicable.

(4) Save in the case of a quarantine notice which takes effect immediately when it is received by the person on whom it is served, a quarantine notice shall give the person on whom it is served a reasonable period within which he, she or it may put forward his, her or its viewpoint on the notice or appeal the notice.

(5) Where appropriate, the Authority shall, without delay, provide a copy of the quarantine notice to the person(s) responsible for regulatory compliance of the manufacturer, the authorised representative, the person responsible in the health institution in respect of the in-house device concerned or the person responsible for the relevant thing or relevant service concerned, and where necessary any importer(s) or distributor(s).

(6) Subject to paragraph (7)(a), a quarantine notice shall give the person on whom it is served a reasonable period within which he or she may put forward his or her viewpoint on the notice or appeal the notice.

(7) A quarantine notice shall take effect—

(a) where required, and where the quarantine notice so declares, immediately when the notice is received by the person on whom it is served, or

(b) in any other case—

(i) where no appeal is taken against the quarantine notice, on expiration of the period referred to in paragraph (6), or

(ii) where an appeal is taken, on the day next following the day on which the quarantine notice is confirmed on appeal or the appeal is withdrawn or on the expiration of the period referred to in paragraph (6), whichever is the later.

(8) The chief executive of the Authority, or another officer of the Authority designated by the chief executive of the Authority for that purpose, may, for stated reasons, revoke or vary a quarantine notice issued by an authorised officer appointed by the Authority.

(9) In the event of non-compliance by the person on whom a quarantine notice has been served, an authorised officer, other than an authorised officer who is an officer of Customs and Excise, shall, with the approval of the chief executive of the Authority, or another officer thereof designated by the chief executive of the Authority for that purpose, take whatever measures are considered necessary to ensure compliance with the quarantine notice, including the seizure, detention and destruction of the device in question or the making of any arrangements for such seizure, detention and destruction or the required cessation of the service.

(10) This Regulation shall not operate to prevent or restrict—

(a) the entitlement of the Authority to take other action to secure compliance with the EU legislation and these Regulations by a person, or

(b) the bringing or prosecuting of any proceedings for an offence under these Regulations.

Compliance notice

30. (1) Where an authorised officer, other than an authorised officer who is an officer of Customs and Excise, is of the opinion that there is non-compliance with a requirement of the EU Regulation or these Regulations, the authorised officer may, following consultation with another officer of the Authority designated by the chief executive of the Authority for that purpose, serve, or arrange to have served, on the person concerned a notice ("compliance notice") in accordance with paragraph (2).

(2) A compliance notice shall—

(a) be signed by the authorised officer issuing it, or the officer consulted in accordance with paragraph (1),

(b) identify the requirement(s) of the EU Regulation or these Regulations with which there has not been compliance,

(c) identify the corrective actions to be taken,

(d) where appropriate, direct the person on whom the compliance notice is served to inform, without delay, the manufacturer, authorised representative, distributor(s) or importer(s) of the device concerned, the health institution of the in-house device concerned or the person responsible for the relevant thing or relevant service concerned of the corrective actions to be taken, and

(e) give a time period, commensurate with the nature of the risk, within which the person on whom the compliance notice is served must take the corrective actions identified pursuant to subparagraph (c).

(3) Where appropriate, the authorised officer shall, without delay, provide a copy of the compliance notice to the person(s) responsible for regulatory compliance of the manufacturer, the authorised representative, the person responsible in the health institution in respect of the in-house device concerned or the person responsible for the relevant thing or relevant service concerned, and where necessary any importer(s) or distributor(s).

(4) Subject to paragraph (5)(a), a compliance notice shall give the person on whom it is served a reasonable period within which he, she or it may put forward his, her or its viewpoint on the notice or appeal the notice.

(5) A compliance notice shall take effect—

(a) where required, and where the compliance notice so declares, immediately when the notice is received by the person on whom it is served, or

(b) in any other case—

(i) where no appeal is taken, on expiration of the period referred to in paragraph (4), or

(ii) where an appeal is taken, on the next day following the day on which the notice is confirmed on appeal or the appeal is withdrawn or on the expiration of the period referred to in paragraph (4), whichever is the later.

(6) The chief executive of the Authority or another officer of the Authority designated by the chief executive of the Authority for that purpose may, for

stated reasons, revoke or vary a compliance notice issued by an authorised officer appointed by the chief executive of the Authority.

(7) In the event of non-compliance with a compliance notice by the person on whom a compliance notice has been served, an authorised officer shall, with the approval of the chief executive of the Authority, or another officer thereof designated by the chief executive of the Authority for that purpose, take whatever measures are considered necessary to ensure compliance with the compliance notice, including the seizure, detention and destruction of the relevant thing or device in question or the required cessation of the relevant service or the making of any arrangements for such seizure, detention, destruction or required cessation.

(8) This Regulation shall not operate to prevent or restrict—

(a) the entitlement of the Authority to take other action to secure compliance with the EU Regulation and these Regulations by a person, or

(b) the bringing or prosecuting of any proceedings for an offence under these Regulations.

Prohibition order

31. (1) Where the Authority is of the opinion that—

(a) there is non-compliance with a requirement of the EU Regulation or these Regulations,

(b) a device, other relevant thing or relevant service presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, or

(c) a person has failed to comply with a compliance notice,

the Authority may serve, or arrange to have served, on the person concerned an order ("prohibition order") in accordance with paragraph (2).

(2) A prohibition order shall—

(a) be signed by the chief executive officer of the authority or another officer thereof authorised for that purpose by the chief executive officer,

(b) state that the Authority is of the opinion that a particular consignment, group, category, batch or lot of the device, relevant thing or relevant service concerned is not in conformity with the EU Regulation or these Regulations,

(c) specify the provision or provisions of the EU Regulation or these Regulations with which the device, relevant thing or relevant service is not in compliance and the matters giving rise to the non-compliance,

(d) where relevant, identify the part or parts of the compliance notice with which there has not been compliance, and

(e) direct the person on whom the prohibition order is served to ensure that—

(i) the device, relevant thing or relevant service is not to be placed on the market, made available on the market, put into service or offered by means of information society services until such time as all appropriate measures, including corrective measures, have been taken to bring the device, relevant thing or relevant service into conformity with the EU Regulation or these Regulations,

(ii) the placing on the market, making available on the market or putting into service of the device or relevant thing or the offering of a relevant service by means of information society services is restricted or made subject to particular requirements,

(iii) the device or relevant thing is prohibited from being placed on the market, made available on the market or put into service,

(iv) the relevant service is prohibited from being offered,

(v) the device or relevant thing is withdrawn or recalled from the market within a specified time-limit,

(vi) the relevant service is withdrawn from the market within a specified time-limit,

(vii) the device or relevant thing is destroyed within a specific time limit and in a manner prescribed by the Authority or is detained for the purposes of destruction by an authorised officer, or

(viii) the relevant service is ceased within a specific time limit and in a manner prescribed by the Authority.

(3) The approval referred to in paragraph (1) may be given orally or in writing and if given orally shall be recorded in writing as soon as practicable.

(4) Where appropriate, the Authority shall, without delay, provide a copy of the prohibition order to the person(s) responsible for regulatory compliance of the manufacturer, the authorised representative, the person responsible in the health institution in respect of the in-house device concerned or the person responsible for the relevant thing or relevant service concerned, and where necessary any importer(s) or distributor(s).

(5) A prohibition order shall take effect—

(a) where the prohibition order so declares, immediately when the order is received by the person on whom it is served, or

(b) in any other case—

(i) where no appeal is taken against the prohibition order, on the expiration of the period during which such an appeal may be taken or the day specified in the prohibition order as the day on which it is to come into effect, whichever is the later, or

(ii) where an appeal is taken, on the next day following the day on which the prohibition order is confirmed on appeal or the appeal is withdrawn or the day specified in the prohibition order as the day on which it is to come into effect, whichever is the later.

(6) The bringing of an appeal against a prohibition order which is to take effect in accordance with paragraph (5)(a) shall not have the effect of suspending the operation of the prohibition order, but the appellant may apply to the Circuit Court to have the operation of the prohibition order suspended until the appeal is disposed of and, on such application, the Circuit Court may, if it thinks it proper to do so, direct that the operation of the prohibition order be suspended until the appeal is disposed of.

(7) In the event of non-compliance by the person on whom the prohibition order has been served, an authorised officer shall, with the approval of the chief executive of the Authority or other officer designated in that behalf by the chief executive of the Authority, take whatever steps are considered necessary to ensure compliance with the direction given under paragraph (2)(e) and this may include the seizure, detention and destruction of the devices or relevant things or the required cessation of relevant services in question or the making of any arrangements for such seizure, detention, destruction or required cessation.

(8) This Regulation shall not operate to prevent or restrict—

(a) the entitlement of the Authority to take other action to secure compliance with the EU Regulation and these Regulations by a person, or

(b) the bringing or prosecuting of any proceedings for an offence under these Regulations.

(9) The chief executive of the Authority may, for stated reasons, revoke or vary a prohibition order made in accordance with this Regulation and the Authority shall be notified at the next available meeting of the Authority of any such revocation or variation and the reasons therefore.

(10) Where a prohibition order has been served and activities are carried on in contravention of the prohibition order, the High Court may, on the application of the Authority, by order prohibit the continuance of the activities.

(11) An application to the High Court for an order under paragraph (10) shall be by motion and the Court, when considering the matter, may make such interim or interlocutory order (if any) as it considers appropriate and the order by which an application under paragraph (10) is determined may contain such terms and conditions (if any) as to the payment of costs as the Court considers appropriate.

Appeals from quarantine notices and compliance notices

32. (1) A person may appeal a quarantine notice or compliance notice served on him, her or it in accordance with appeals procedures provided in guidelines published by the Authority.

(2) The Authority shall inform a person of his or her right of appeal, and the applicable time limits, when serving him, her or it with a quarantine notice or compliance notice.

(3) A person who is aggrieved by a decision on an appeal under paragraph (1) may appeal that decision to the District Court in the district court district in

which the quarantine notice or compliance notice was served, not later than 7 days after the decision concerned.

(4) The bringing of an appeal under this Regulation against a notice which is to take effect immediately on service shall not have the effect of suspending the operation of the notice, but the appellant may apply—

(a) in the case of an appeal under paragraph (1), in accordance with the procedures referred to therein, or

(b) in the case of an appeal under paragraph (3), to the District Court, to have the operation of the quarantine notice or compliance notice concerned suspended until the appeal is disposed of.

(5) The District Court shall, upon an appeal under paragraph (3), do one of the following:

(a) affirm the notice concerned;

(b) direct the Authority to withdraw the notice concerned; or

(c) direct the Authority to modify the notice concerned.

(6) The Authority shall comply with a direction under paragraph (5)(b) or (c).

(7) Where on the hearing of an appeal under paragraph (3) a notice is affirmed, notwithstanding Regulation 29(7) or 30(5), as applicable, the judge of the District Court by whom the appeal is heard may, on the application of the appellant, suspend the operation of the notice for such period as in the circumstances of the case the district judge considers appropriate.

(8) A person who appeals under paragraph (3) or who applies for a direction under paragraph (7) shall at the same time notify the Authority of the appeal or application and the grounds for the appeal or application and the Authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal or application.

(9) A decision of the District Court on an appeal under paragraph (3) shall be final.

Appeals from prohibition orders

33. (1) A person may appeal a prohibition order served on him, her or it, to the Circuit Court in the circuit in which the order was served, not later than 7 days after the service of the notice or order concerned.

(2) The bringing of an appeal under this Regulation against a prohibition which is to take effect immediately on service shall not have the effect of suspending the operation of the order, but the appellant may apply to the Circuit Court to have the operation of the order suspended until the appeal is disposed of and, on such application, the Court may, if it thinks it proper to do so, direct that the operation of the order be suspended until the appeal is disposed of.

(3) The Circuit Court shall, upon an appeal under this Regulation, do one of the following:

(a) affirm the order concerned;

(b) direct the Authority to withdraw the order concerned; or

(c) direct the Authority to modify the order concerned.

(4) The Authority shall comply with a direction under paragraph (3)(b) or (c).

(5) Where on the hearing of an appeal under this Regulation an order is affirmed, notwithstanding paragraph Regulation 31(5), as applicable, the judge of the Circuit Court by whom the appeal is heard may, on the application of the appellant, suspend the operation of the order for such period as in the circumstances of the case the judge considers appropriate.

(6) A person who appeals under this Regulation or who applies for a direction under paragraph (5) shall at the same time notify the Authority of the appeal or application and the grounds for the appeal or application and the Authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal or application.

(7) A decision of the Circuit Court on an appeal under this Regulation shall be final, save

that, by leave of the Court an appeal from the decision shall lie to the High Court on a specified question of law.

Destruction and disposal

34. Where—

(a) any relevant thing, book, record, document, or premises is detained under this Part, but is not the subject of a prosecution, and
  (i) no claim is made for its return within 28 days of notice in writing being given of the intention to destroy or dispose of same, or render same inoperable, or
  (ii) the supplier of the relevant thing is not reasonably identifiable, or
(b) a device being supplied at a distance by information society services in contravention of the EU Regulation is detained,

an authorised officer may destroy or dispose of, or render inoperable, such thing, book, record, document, premises or device, in the interest of the protection of public health.

Suspension, restriction and withdrawal of designation of notified bodies

35. Where the Authority has ascertained that a notified body—

(a) no longer meets the applicable requirements set out in the EU Regulation,
(b) is failing to fulfil its obligations, or
(c) has not implemented necessary corrective measures,

the Authority shall suspend, restrict or fully or partially withdraw the notified body's designation, in accordance with Article 42(4) of the EU Regulation.

Service of notices and orders

36. (1) A notice or order served or given by or under this Part shall be addressed to the person concerned and served or given in one of the following manners:

(a) by addressing it to the person by name and delivering it to him or her;

(b) by leaving it at the address at which the person ordinarily resides or carries on business;

(c) by sending it by post in a prepaid registered letter addressed to the person at the address at which he or she ordinarily resides or carries on business;

(d) if an address for the service of notices has been furnished by the person, by leaving it at, or sending it by prepaid registered post addressed to him or her to, that address;

(e) where the address at which the person ordinarily resides or carries on business cannot be ascertained by reasonable inquiry and notice is required to be served on, or given to, him or her in respect of any premises by delivering it to a person over the age of 16 years resident in or employed on the premises, or by affixing it in a conspicuous position on or near the premises; or

(f) by sending it by means of electronic mail to a facility for the reception of electronic mail where such an electronic mail address has been furnished by the person, but only if the sender's facility for the reception of electronic mail generates a message confirming a receipt of the electronic mail confirming successful transmission of the notice.

(2) Where the name of the person concerned cannot be ascertained by reasonable inquiry, a notice or order under this Part may be addressed to "the occupier", "the owner" or "the person in charge", as the case may be.

(3) For the purposes of this Regulation, a company within the meaning of the Companies Act 2014 (No. 38 of 2014) shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

(4) A person shall not at any time during the period of 3 months after a notice is affixed under paragraph (1)(e) remove, damage or deface the notice without lawful authority.

PART 6

REVOCATIONS AND TRANSITIONAL PROVISIONS

Revocations

37. The following are revoked:

(a) the Regulations of 2001;

(b) the European Communities (Medical Devices) (Amendment) Regulations 2002 (S.I. No. 576 of 2002), other than Regulation 3 thereof;
(c) the European Communities (In Vitro Diagnostic Medical Devices) (Amendment) Regulations 2012 (S.I. No. 207 of 2012);
(d) the European Communities (*In Vitro* Diagnostic Medical Devices) (Amendment) Regulations 2020 (S.I. No. 145 of 2020);
(e) the European Communities (*In Vitro* Diagnostic Medical Devices) (Amendment)(No. 2) Regulations 2020 (S.I. No. 302 of 2020).

Transitional provisions

38. (1) Notwithstanding the provisions of these Regulations—

(a) a person is not guilty of an offence by reason of relying upon a certificate issued by a notified body in accordance with the Directive (other than a certificate issued in accordance with Annex VI to the Directive) prior to 25 May 2017 provided that the period indicated on the certificate has not expired,
(b) until 27 May 2025, a person is not guilty of an offence by reason of relying upon a certificate issued by a notified body in accordance with Annex VI to the Directive prior to 25 May 2017 provided that the period indicated on the certificate has not expired,
(c) until 27 May 2025, a person is not guilty of an offence by reason of relying upon a certificate issued by a notified body in accordance with the Directive on or after 25 May 2017 provided that the period indicated on the certificate has not expired,
(d) a person is not guilty of an offence by reason of placing on the market or putting into service, on or before 26 May 2025, a class D device for which the conformity assessment procedure pursuant to the Directive did not require the involvement of a notified body, for which a declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to the EU Regulation requires the involvement of a notified body or any device which has a certificate that was issued in accordance with the Directive and that is valid by virtue of Article 110(2) of the EU Regulation, provided that—
    (i) from 26 May 2022 the device continues to comply with the Directive,
    (ii) there are no significant changes in the design and intended purpose of the device, and
    (iii) the requirements of the EU Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are complied with in place of the corresponding requirements in the Directive,

(e) a person is not guilty of an offence by reason of placing on the market or putting into service, on or before 26 May 2026, a class C device for which the conformity assessment procedure pursuant to the Directive did not require the involvement of a notified body, for which a declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to the EU Regulation requires the involvement of a notified body, provided that—

(i) from 26 May 2022 the device continues to comply with the Directive,

(ii) there are no significant changes in the design and intended purpose of the device, and

(iii) the requirements of the EU Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are complied with in place of the corresponding requirements in the Directive,

(f) a person is not guilty of an offence by reason of placing on the market or putting into service, on or before 26 May 2027, a class B device or a class A device placed on the market in sterile condition, for which the conformity assessment procedure pursuant to the Directive did not require the involvement of a notified body, for which a declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to the EU Regulation requires the involvement of a notified body, provided that—

(i) from 26 May 2022 the device continues to comply with the Directive,

(ii) there are no significant changes in the design and intended purpose of the device, and

(iii) the requirements of the EU Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are complied with in place of the corresponding requirements in the Directive,

(g) until 26 May 2025, a person is not guilty of an offence by reason of making available on the market or putting into service a device lawfully placed on the market pursuant to the Directive prior to 26 May 2022,

(h) a person is not guilty of an offence by reason of making available on the market or putting into service a device lawfully placed on the market from 26 May 2022 pursuant to Article 110 of the EU Regulation,

(i) until 26 May 2026, for devices referred to in the second subparagraph or in the third subparagraph, point (a) of paragraph 3 of that Article;

(ii) until 26 May 2027, for devices referred to in the third subparagraph, point (b) of paragraph 3 of that Article;

(iii) until 26 May 2028, for devices referred to in the third subparagraph, points (c) and (d) of paragraph 3 of that Article,

(i) A sponsor is not guilty of an offence by reason of the continuance of a performance evaluation which was commenced in accordance with Article 9(4) and 10(1) of the Directive before 26 May 2022, provided that the reporting of serious adverse events and device deficiencies is carried out in accordance with the EU Regulation,

(j) Notwithstanding subparagraphs (d)(i), (e)(i) and (f)(i) of paragraph (1) of this Regulation, a person is not guilty of an offence if they comply with Article 26(3), Article 28(1) and Article 51(5) of the EU Regulation rather than Article 10 and points (a) and (b) of Article 12(1) and Article 15(5) of the Directive as specified in Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices,[10] during the period starting on the later of the dates referred to in point (f) of Article 113(3) and ending 18 months later.

(2) Notwithstanding Regulation 37, until six months after the Eudamed functionality date, Regulation 7 and 23 (inserted by Regulation 2 of the European Communities (*In Vitro* Diagnostic Medical Devices) (Amendment) (No. 2) Regulations 2020) of the Regulations of 2001, continue to apply as if they had not been revoked, for the purposes of information and data exchange only, and a person who fails to comply with same is guilty of an offence.

(3) Notwithstanding Regulation 37 —

(a) Regulations 7(5) and 10(1)(b)(ii) of the Regulations of 2001 shall continue to apply, as if they had not been revoked, in respect of performance evaluations which were commenced in accordance with Articles 9(4) and 10(1) of the Directive and Regulation 7(5) of the Regulations of 2001 before 26 May 2022, and

(b) a device which has been authorised by the Authority in accordance with Regulation 8(11) of the Regulations of 2001 shall keep the validity indicated in the authorisation.

(4) Notwithstanding Regulation 37, Regulation 11(4), (5) and (6) of the Regulations of 2001 continue to apply, as if they had not been revoked, in respect of—

(i) devices granted CE Marking approval thereunder and made available on the market or put into service , and

(ii) the means by which information is to be exchanged with and notifications to the Authority,up until six months after the Eudamed functionality date.

(5) Notwithstanding Regulation 37, as regards the devices referred to in subparagraphs

[10] OJ L 102, 23.4.2010, p. 45.

(d) to (h) of paragraph (1), the Regulations of 2001, continue to apply until the associated timelines set out therein to the extent necessary for the application of Articles 110(3) and (4) of the EU Regulation, as if the Regulations of 2001 had not been revoked.

(6) Notwithstanding the provisions of these Regulations, until 6 months after the Eudamed functionality date, the offences in—

(a) Regulation 14(1)(m), (y), (aa), (bb), (cc), (dd), (ee), (ff), (gg) and (jj),

(b) Regulation 15(e) and (f),

(c) Regulation 17(j),

(d) Regulation 18(c) and (d),

(e) Regulation 21(2)(l), (m), (n), (o), (p), (q) and (r),

(f) Regulation 21(6)(a) and (d),

do not apply, but only insofar as they apply to the obligations and requirements that relate to Eudamed, including using Eudamed as the mechanism for information exchange.

(7) Notwithstanding the provisions of these Regulations, until 24 months after the Eudamed functionality date, the offence in Regulation 17(k) does not apply.

(8) Notwithstanding the provisions of these Regulations, until 24 months after the Eudamed functionality date, the offences in Regulation 19(u) and (x) do not apply, but only insofar as they apply to the obligations and requirements that relate to Eudamed, including using Eudamed as the mechanism for information exchange.

(9) Notwithstanding the provisions of these Regulations—

(a) until 26 May 2023, for Class D devices, and

(b) until 26 May 2025, for Class B and C devices, and

(c) until 26 May 2027, for class A devices, the offence in Regulations 14(w) does not apply.

(10) Notwithstanding the provisions of these Regulations —

(a) until May 2024, the offence in Regulation 20(b) does not apply insofar as it relates to Article 5(5), (b) (c) and (e) to (i) of the EU Regulations,

(b) until May 2028, the offence in Regulation 20(b) does not apply insofar as it relates to Article 5(5)(d) of the EU Regulation.

(11) In this Regulation –

"Eudamed functionality date" means the date of publication of the notice referred to in Article 34(3) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5

April 2017[11], as amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020[12].

L.S.

GIVEN under my Official Seal,
25 May, 2022.

STEPHEN DONNELLY,
Minister for Health.

[11] OJ No. L 117, 5.5.2017, p. 1.
[12] OJ No. L 130, 24.4.2020, p. 18.

EXPLANATORY NOTE

(*This note is not part of the Instrument and does not purport to be a legal interpretation*.)

These Regulations—

- confer functions on the Health Products Regulatory Authority in relation to *in vitro* diagnostic medical devices,

- set out certain requirements which apply where a genetic test is used on individuals in the context of healthcare,

- provide for various matters in relation to performance studies of *in vitro* diagnostic medical devices, and

- provide offences for breaches of the requirements of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, as amended by Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 and provisions herein.

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