The Government of Romania

EMERGENCY ORDINANCE
no. 137 of 12 October 2022

on establishment of the institutional framework, as well as the measures necessary for the implementation of the provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

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***) Important note:**
For entry into force of Articles 17 - 19, see the provisions of Art. 20.

In order to ensure compliance with the obligation of the Romanian State to adopt the necessary measures for the implementation of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, hereinafter referred to as ***Regulation (EU) 2017/746***, directly applicable in all Member States,

considering the need to urgently adopt at national level the legal provisions to establish a regulatory framework, administrative mechanisms and appropriate tools for the effective implementation of Regulation (EU) 2017/746,

having regard to the provisions of Article 113(2) of Regulation (EU) 2017/746, according to which the deadline for the application of the provisions of this Regulation is 26 May 2022, and the Member States of the European Union must take all necessary measures to ensure that the provisions of Regulation (EU) 2017/746 are implemented, also by establishing effective, proportionate and dissuasive sanctions for infringements thereof,

having regard to the need to correlate and harmonise national legislation with European Union legislation in the field of in vitro diagnostic medical devices, in order to ensure adequate and effective compliance with Regulation (EU) 2017/746 by establishing implementing measures to ensure the proper functioning of the internal market as regards in vitro diagnostic medical devices, taking as a basis a high level of safety and health protection for patients and users and taking into account small and medium-sized enterprises active in this area, while supporting innovation and ensuring, inter alia, that data resulting from performance studies are reliable and robust and that the safety of subjects participating in performance trials is protected, through primary regulatory documents,

Considering that the lack of immediate legislative intervention regarding the establishment of national rules on in vitro diagnostic medical devices has the effect of creating a state of legal uncertainty and the Romanian State's failure to fulfil the obligations arising from the implementation of Regulation (EU) 2017/746, especially since this Regulation establishes high quality and safety standards for in vitro diagnostic medical devices, in order to respond to common safety concerns regarding such products, and also harmonises the rules for the placing on the market and putting into service of in vitro diagnostic medical devices and their accessories on the European Union market,

considering that the delegated legislation - constitutionally legitimised in various cases that required the harmonisation of national legislation with EU legislation in view of the need to avoid the European Commission initiating sanctioning procedures - ensures, promptly and effectively, the fulfilment by Romania of its obligations as a Member State of the European

Union, aiming at the adoption of legislative measures for full implementation of Regulation (EU) 2017/746,

whereas the absence of an adequate legal framework may have negative consequences consisting in the risk of the European Commission initiating a possible procedure regarding the failure to fulfil the obligations that Romania has as a Member State of the European Union, and the obstruction of the implementation of Regulation (EU) 2017/746, so as to ensure compliance with the principle of free movement of goods, represents a reason for initiating such a procedure,

taking into account as well the fact that failure to promote the regulatory act in an emergency regime may have negative consequences, given that transparency and adequate access to information need to be properly presented to the intended user,

taking into account the fact that failure to promote the regulatory act in an emergency regime would bring serious harm with long-term effects on the health of the population, for implementation of high quality and safety standards for in vitro diagnostic medical devices, thus ensuring a high level of protection of the health and safety of patients, users and other persons,

considering that these elements concern the general public interest and represent an extraordinary situation, the regulation of which cannot be postponed, requiring the adoption of immediate measures by means of an Emergency Ordinance,

pursuant to Art. 115 paragraph (4) of the Constitution of Romania, republished,

the Government of Romania hereby adopts this Emergency Ordinance.

Art. 1 - (1) This Government Ordinance establishes the institutional framework, as well as the measures necessary for the implementation of the provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, hereinafter referred to as ***the Regulation*.**

(2) The terms used in this Emergency Ordinance have the meaning provided for in Article 2 of the Regulation.

(3) For the purpose of the provisions of this Emergency Ordinance, ***public and private healthcare institutions*** shall refer to the state or private healthcare units provided for in Art. 2 paragraph (6) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented.

Art. 2 - The National Agency for Medicines and Medical Devices of Romania, hereinafter referred to as the NAMMDR, is hereby appointed the competent authority in the field of in vitro diagnostic medical devices, as well as the market surveillance authority in this field.

Art. 3 - (1) The information provided by the manufacturer or the authorised representative, together with the in vitro diagnostic medical device, provided for in point 20 of Annex I to the Regulation, will be presented in Romanian, without excluding their presentation in other official languages of the European Union.

(2) The information provided for in paragraph (1) may be provided, for justified reasons, in English for in vitro diagnostic medical devices intended exclusively for professionals, only with their written consent, based on approval of the NAMMDR.

(3) Information provided, as part of a software system, by the user interface of professional equipment, as defined in Art. 2 point 30 of the Regulation, may be provided, for justified reasons, in English, only with the written consent of the user. For self-testing equipment, the interface must be in Romanian.

(4) The methodological rules for the application of the provisions of paragraphs (2) and (3) shall be approved through Order of the Minister of Health.

(5) Upon request of the NAMMDR, the manufacturer or the authorised representative shall submit all information and documentation necessary to demonstrate the device's conformity. The documents shall be drawn up in Romanian for manufacturers headquartered in Romania

or in English and translated into Romanian for manufacturers headquartered outside Romania.

(6) In vitro diagnostic medical devices may be made available on the market only until the date on which the respective device can be used safely, according to the information on the label in accordance with the provisions of point 20.2 points h) and i) of Annex I to the Regulation.

(7) Upon request of the NAMMDR, the notified body headquartered in Romania shall make available to the NAMMDR all documents relating to the procedures provided for in Art. 48 paragraphs (1) - (10) of the Regulation or only some of them, including technical documentation, audit, assessment and inspection reports, in Romanian or, with the approval of the NAMMDR, in English, according to the methodological rules for application of the provisions of this Article, which shall be approved through Order of the Minister of Health.

(8) Certificates issued by notified bodies headquartered in Romania, according to the provisions of Annexes IX - XI to the Regulation, shall be drawn up in Romanian as well.

(9) In accordance with the provisions of Article 17(1) of the Regulation, the manufacturer's EU declaration of conformity shall be translated into Romanian or English.

Art. 4 - (1) For the purpose of export, at the request of a manufacturer headquartered in Romania or of the manufacturer's authorised representative, headquartered in Romania, the NAMMDR issues a free sale certificate, in accordance with the provisions of Art. 55 of the Regulation.

(2) The NAMMDR charges fees for issuing the free sale certificate, in accordance with the Order of the Minister of Health on the approval of the fees charged by the NAMMDR for activities carried out in the field of medical devices.

(3) The procedural rules for the application of the provisions of this article shall be approved through Order of the Minister of Health.

Art. 5 - The list of Romanian standards that adopt the harmonised European standards in the field of in vitro diagnostic medical devices falling under the scope of the Regulation is approved through Order of the Minister of Health.

Art. 6 - (1) The identification and traceability of in vitro diagnostic medical devices, other than those subject to performance studies, shall be achieved through the unique identification system of a medical device, hereinafter referred to as the ***UDI***, in accordance with Art. 24 paragraph (1) of the Regulation.

(2) Economic operators are obliged, according to the provisions of Art. 24 paragraph (8) of the Regulation, to store and keep, in electronic format, the UDI of the in vitro diagnostic medical devices that they have supplied and that have been supplied to them, in the event that the European Commission has adopted an implementing act in this regard, according to the provisions of Art. 24 paragraph (11) point a) of the Regulation.

(3) Public and private health institutions in Romania are required to store and keep, in electronic format, the UDIs of the in vitro diagnostic medical devices in the category of those provided for in paragraph (2), which have been supplied to them.

Art. 7 - (1) The NAMMDR ensures centrally, at national level, the registration of any reporting carried out by manufacturers of in vitro diagnostic medical devices, except for those which are subject to performance studies, regarding:

a) any serious incident as defined in Art. 2 point 68 of the Regulation;

b) any corrective action in the field safety area.

(2) The obligation to report to the NAMMDR the serious incidents mentioned in paragraph (1) point a) lies with the manufacturers of in vitro diagnostic medical devices, in compliance with the deadlines provided for in Art. 82 of the Regulation.

(3) In order to report serious incidents, as provided for in paragraph (1) point a), as well as for field safety corrective actions, as provided for in paragraph (1) point b), manufacturers shall use the forms made available by the European Commission.

(4) In order to report serious incidents, as provided for in paragraph (1) point a), healthcare professionals, patients and users shall use the form, the model of which shall be approved through Order of the Minister of Health.

(5) Public and private healthcare institutions in Romania shall report to the NAMMDR serious incidents involving the use of an in vitro diagnostic medical device manufactured within them, for their own use, and the corrective measures taken.

(6) The NAMMDR shall centrally assess, at national level, if possible and the manufacturer and, where appropriate, with the notified body concerned, any information relating to a serious incident which has occurred on the Romanian territory or to a field safety corrective action that has been taken or is to be taken on the Romanian territory and which is brought to its attention in accordance with Art. 82 of the Regulation.

(7) The field safety notification provided for in Article 84(8) of the Regulation shall be drawn up in both English and Romanian and shall be made available without delay to the users of the in vitro diagnostic medical device in question.

(8) For in vitro diagnostic medical devices used exclusively by healthcare professionals, at their request, the field safety notification provided for in Article 84(8) of the Regulation may be made available to them only in English.

Art. 8 - (1) In line with the provisions of Article 54 of the Regulation, the NAMMDR may authorise, on the basis of a duly justified request, the placing on the market or putting into service on the Romanian territory of a specific in vitro diagnostic device, for which the procedures referred to in that Article have not been performed, but whose use is in the interest of public health, safety or health of patients.

(2) The methodological rules for the application of the provisions of this article shall be approved through Order of the Minister of Health.

Art. 9 - (1) The NAMMDR verifies the data entered by manufacturers, authorised representatives and importers of in vitro diagnostic medical devices, pursuant to the provisions of Art. 28 paragraph (1) of the Regulation, and obtains from the electronic system provided for in Art. 27 of the Regulation a unique registration number, which it transmits to them.

(2) The NAMMDR charges fees for the introduction and maintenance of economic operators into the databases, according to the provisions of the Order of the Minister of Health provided for in Art. 4 paragraph (2).

(3) The methodological rules for the application of the provisions of this Article shall be approved through Order of the Minister of Health.

Art. 10 - The methodological rules for the application of the provisions of Article 5 paragraph (5) of the Regulation, regarding the manufacture and use for their own purposes of in vitro diagnostic medical devices by public and private health institutions, shall be approved through Order of the Minister of Health.

Art. 11 - Any type of activity carried out for diagnostic or treatment purposes, even when the values obtained as a result of the health assessment are informative, regardless of whether the activity is carried out in a medical office, in a health institution, in complementary medicine centers, in spaces specially designed for such activities carried out on a mobile basis or through information society services, for which various equipment used in vitro for examination of samples, including donated blood and tissues, derived from the human body, as defined in Art. 2 of the Regulation, is considered to be carried out for medical purposes and only in vitro diagnostic medical devices will be used in this regard.

Art. 12 - (1) The methodological rules regarding clinical evidence, performance evaluation and performance-related studies regulated by the provisions of Articles 56 - 76 of the Regulation shall be approved through Order of the Minister of Health.

(2) The NAMMDR charges fees for carrying out the activity of approval of performance evaluation procedure and performance-related studies, according to the provisions of the Order of the Minister of Health provided for in Art. 4 paragraph (2).

Art. 13 - (1) Healthcare institutions that use a genetic test in healthcare and for the medical purpose of diagnosis, treatment improvement or preventive or prenatal testing have the obligation to inform the tested person prior to the use of such a test, through a physician or other persons with specialised training, of the possible risks and consequences on the physical, psychological, family, professional and social level, resulting from the use of such a test, namely: the risks, limitations and benefits of testing or not testing; alternatives to genetic

testing; details about the testing process; confidentiality of test results; voluntary nature of testing and potential consequences related to the results.

(2) The manners of counselling the tested person or, if applicable, their designated legal representative, as well as for obtaining informed consent, are approved through Order of the Minister of Health.

(3) The processing of personal data obtained for the purposes set out in paragraph (1) by healthcare institutions shall be carried out in compliance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), of Law No. 190/2018 on implementing measures for Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), as amended, as well as other specific regulations in the field of data protection.

Art. 14 - (1) Advertising for in vitro diagnostic medical devices includes any form of information through direct contact, as well as any form of promotion intended to stimulate the distribution, sale or use of in vitro diagnostic medical devices.

(2) The NAMMDR is the competent authority for evaluation, notification and approval of advertising materials, as well as any other form of advertising regarding in vitro diagnostic medical devices.

(3) The procedural rules for the application of the provisions of this Article shall be approved through Order of the Minister of Health.

Art. 15 - (1) The NAMMDR is designated as the authority responsible for notified bodies, in accordance with Art. 31 of the Regulation.

(2) The application for designation of a notified body shall be submitted to the NAMMDR by conformity assessment bodies in accordance with Art. 34 of the Regulation.

(3) The application for designation or the application for extension of the scope provided for in Art. 35 paragraph (7) of the Regulation, the corresponding documents and their assessment must be drawn up in Romanian or, with the agreement of the NAMMDR, in English.

(4) The notified bodies shall inform the NAMMDR without delay, within maximum 15 days, of any relevant change which could affect compliance with the requirements set out in Annex VII of the Regulation or their ability to carry out the conformity assessment activities related to the medical devices for which they have been designated, in accordance with Art. 40 of the Regulation.

(5) The NAMMDR, if it finds that a notified body no longer meets the requirements set out in Annex VII of the Regulation, that it does not fulfil its obligations or that it has not implemented the necessary corrective measures, shall suspend, restrict or withdraw, in part or in full, the designation, depending on the seriousness of the failure to meet those requirements or to fulfil those obligations.

(6) The procedural rules for the application of the provisions of this Article shall be approved through Order of the Minister of Health.

(7) The NAMMDR shall charge fees for carrying out the activity of appointing and monitoring notified bodies in accordance with the provisions of the Order of the Minister of Health provided for in Art. 4 paragraph (2).

(8) The NAMMDR shall annually prepare the report provided for in Art. 40 paragraph (12) of the Regulation, which it shall submit to the European Commission and the Medical Device Coordination Group.

(9) The report provided for in paragraph (8) shall contain a summary which is intended for publication and shall be uploaded to the European Database on Medical Devices, hereinafter referred to as the ***Eudamed***, through the electronic system provided for in Article 52 of the Regulation.

Art. 16 - (1) In fulfilling its obligations specified in Article 88 of the Regulation, the

NAMMDR shall review and evaluate the performance of market surveillance activities in the field of in vitro diagnostic medical devices, every four years. The results of each evaluation shall be recorded in a report, which shall be transmitted to the European Commission and the Member States.

(2) The report provided for in paragraph (1) shall contain a summary intended for publication, which shall be uploaded into the electronic system provided for in Article 95 of the Regulation.

(3) In fulfilling the obligations laid down in Article 90 of the Regulation, the NAMMDR shall immediately inform the European Commission and the other Member States, by means of the electronic system referred to in Article 95 of the Regulation, of any additional relevant information at its disposal relating to the non-compliance of the device concerned and of any measures taken in relation to the device concerned.

Art. 17 - The following acts are contraventions, to the extent that they are not committed under other conditions that would be considered, according to criminal law, crimes:

a) failure by manufacturers or their authorised representatives to comply with the provisions of Articles 5 (1) and (2) of the Regulation on placing on the market or putting into service and the fulfilment of the general safety and performance requirements set out in Annex I of the Regulation applicable to the in vitro diagnostic medical device, taking into account its intended purpose;

b) failure to comply with the provisions of Article 5(1) of the Regulation regarding the failure of importers and suppliers to meet the requirements regarding the supply, installation, maintenance and proper use of the in vitro diagnostic medical device, taking into account its intended purpose;

c) failure by healthcare institutions to comply with the provisions of Article 5 paragraph (5) of the Regulation regarding in vitro diagnostic medical devices manufactured and used only within public and private health institutions;

d) failure to comply with the provisions of Article 6, paragraphs (1) - (3) of the Regulation regarding the failure of importers and suppliers to meet the requirements regarding the conformity of the in vitro diagnostic medical device with the provisions of the Regulation and the possession of a copy of the EU declaration of conformity of the medical device offered through distance sale of medical devices;

e) failure to comply with the provisions of Art. 6 paragraph (2) and (3) of the Regulation regarding the failure by manufacturers or public and private health institutions to meet the requirements regarding the conformity of the medical device for in vitro diagnosis offered through distant selling of medical devices with the provisions of the Regulation and the possession of a copy of the EU declaration of conformity of the medical device offered through distant selling of medical devices;

f) manufacturer’s failure, its authorised representative, importer or distributor to comply with the provisions of Article 7 of the Regulation, concerning the prohibition of the use on labels, in the instructions for use, in making available, putting into service and advertising of in vitro diagnostic medical devices, of texts, names, trademarks, images and figurative or other signs which could mislead the user or patient as to the intended purpose, safety and performance of the in vitro diagnostic medical device;

g) failure by manufacturers or their authorised representatives to comply with the provisions of Article 10, paragraphs (1) - (15) of the Regulation, when placing their in vitro diagnostic medical devices on the market or putting them into service;

h) manufacturer’s failure of a device not headquartered in a Member State to comply with the provisions of Article 11(1) - (6) of the Regulation, relating to the designation of a single authorised representative;

i) failure to comply with the provisions of Article 13 of the Regulation, relating to the general obligations of importers when placing in vitro diagnostic medical devices on the European Union market;

j) failure to comply with the provisions of Article 14 of the Regulation, relating to the general obligations of suppliers when making in vitro diagnostic medical devices available on

the European Union market;

k) manufacturers' failure to comply with the provisions of Article 15, paragraphs (1) and (2) of the Regulation, relating to the obligation to have a person responsible for compliance with the regulations at their disposal;

l) authorised representatives' failure to comply with the provisions of Art. 15 paragraph (6) of the Regulation, regarding the obligation to permanently and uninterruptedly have at their disposal at least one person responsible for compliance with the regulations;

m) failure to comply with the provisions of Article 16 of the Regulation, regarding cases in which the obligations of manufacturers apply to importers, suppliers or other persons who assume the obligations incumbent on manufacturers;

n) manufacturers' failure to comply with the provisions of Article 17 (1) - (3) of the Regulation, relating to the information contained in the EU declaration of conformity, as set out in Annex IV of the Regulation;

o) manufacturers' failure to comply with the provisions of Article 18 of the Regulation, regarding the application of the CE conformity marking;

p) the economic operator's failure to comply with the provisions of Art. 19 paragraph (2) and (3) of the Regulation, relating to in vitro diagnostic medical devices which are subject to a performance study and in vitro diagnostic medical devices intended solely for presentation or demonstration at trade fairs, exhibitions, demonstrations or similar events, where the necessary conditions for the performance study provided for in Art. 70 of the Regulation are not met;

q) failure to comply with the provisions of Article 20 of the Regulation, concerning the obligations of natural or legal persons who make available on the market an article specifically intended to replace an identical or similar part or integral component of an in vitro diagnostic medical device that is defective or worn out, in order to maintain or restore the function of the medical device without changing its performance or safety characteristics or its intended purpose to ensure that the article does not affect the safety and performance of the in vitro diagnostic medical device in question;

r) failure to comply with the provisions of Art. 22 paragraph (2) of the Regulation, relating to the obligations of economic operators to identify and communicate, at the request of the NAMMDR, information regarding the supply chain of in vitro diagnostic medical devices;

s) failure to comply with the provisions of Art. 24 paragraphs (3), (4), (6) and (7) of the Regulation, relating to the manufacturer's obligations to assign to the in vitro diagnostic medical device and, where applicable, to all higher levels of packaging a UDI created in accordance with the rules of the issuing entity designated by the European Commission, in accordance with Art. 27 paragraph (2) of the Regulation, to apply and maintain a list of all assigned UDIs, before placing an in vitro diagnostic medical device on the market;

ş) manufacturers' failure by to comply with the provisions of Art. 26 of the Regulation, relating to the registration of in vitro diagnostic medical devices;

t) importers' failure by to comply with the provisions of Art. 27 paragraph (3) of the Regulation, relating to the electronic system for the registration of economic operators;

ţ) failure to comply with the provisions of Art. 28 paragraphs (1), (4) and (5) of the Regulation, relating to the obligation to register manufacturers, authorised representatives and importers, prior to the placing on the market of an in vitro diagnostic medical device;

u) failure to comply with the provisions of Art. 40 paragraph (1) of the Regulation, regarding the notification to the NAMMDR without delay, within maximum 15 days, by notified bodies, of any relevant change that could affect compliance with the requirements of Annex VII of the Regulation or their ability to carry out the conformity assessment activities related to in vitro diagnostic medical devices for which they have been designated;

v) manufacturer's failure to comply with the provisions of Art. 48 paragraph (1) - (4), (7) - (10) of the Regulation, relating to conformity assessment and conformity assessment procedures;

w) manufacturer's failure to comply with the provisions of Art. 56 paragraph (1) - (6) of

the Regulation relating to the planning, carrying out and documentation of the performance evaluation;

x) sponsor's failure to comply with the provisions of Art. 66 paragraph (1), Art. 68 paragraph (1), Art. 71 paragraph (1) and (3), Art. 73 paragraph (1) and (3) - (5) and of Art. 76 paragraph (1) - (4) of the Regulation relating to the submission of the application for the performance study and the monitoring of its performance;

y) investigator's failure to comply with the provisions of Article 68 paragraph (1) of the Regulation regarding making sure that the clinical investigation is conducted in accordance with the approved clinical investigation plan;

z) manufacturer's failure to comply with the provisions of Article 78, paragraphs (1) and (4) of the Regulation, relating to the planning, establishment, documentation, implementation, management and updating of a post-market surveillance system, as well as taking preventive or corrective actions or both;

aa) manufacturer's failure to comply with the provisions of Article 80 of the Regulation, relating to the preparation of the post-marketing surveillance report, the justification and description of any preventive and corrective actions taken, as well as the updating of the report;

ab) manufacturer's failure to comply with the provisions of Article 81 of the Regulation regarding the preparation of the updated periodic safety report, the justification and description of any preventive and corrective actions taken, as well as the updating of the report;

ac) manufacturer's failure to comply with the provisions of Article 82(1) - (9) of the Regulation, relating to the obligation to report serious incidents and field safety corrective actions for in vitro diagnostic medical devices made available on the EU market;

ad) manufacturer's failure to comply with the provisions of Article 84 (1), (3), (5) and (8) of the Regulation, relating to the analysis of serious incidents and field safety corrective actions for in vitro diagnostic medical devices made available on the EU market;

ae) failure to comply with the provisions of Article 90(3) of the Regulation, concerning the obligations of economic operators to ensure without delay that, within the European Union, all appropriate corrective actions are taken in respect of all in vitro diagnostic medical devices that they have made available on the market which present an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of public health protection;

af) manufacturer's or the authorised representative's failure to comply with the provisions of Article 3, paragraphs (1) - (3) and (9), relating to the information provided;

ag) economic operators' failure to comply with the provisions of Art. 3 paragraph (6) regarding the validity period;

ah) economic operators' failure to comply with the provisions of Article 6 paragraph (2) regarding the storage, in electronic format, of the UDI of the in vitro diagnostic medical device that they have supplied and/or that has been supplied to them, as the case may be;

ai) failure by public and private healthcare institutions to comply with the provisions of Art. 6 paragraph (3) regarding the storage, in electronic format, of the UDI of the in vitro diagnostic medical device that was provided to them;

aj) users' failure to comply with the provisions of Art. 11, regarding the use of only in vitro diagnostic medical devices in the activity carried out in a medical office/health institution, in complementary medicine centers, bioresonance offices or even in spaces specially arranged for such activities carried out on a mobile basis, for which various equipment for medical purposes is used;

ak) public and private health institutions' failure to comply with the obligations provided for in Art. 13 paragraph (1) regarding counselling of the tested person or, if applicable, of their designated legal representative;

al) the introduction and making available on the market by economic operators of devices classified by manufacturers in a category other than that of in vitro diagnostic medical devices, for the purpose of using them for the examination of human-derived samples and which by their nature have a purpose similar to that described in Art. 2 point 2 of the

Regulation.

Art. 18 - (1) The infringements mentioned in Art. 17 points a), n) and o) are sanctioned by a fine of 10,000 to 20,000 lei, as well as by the prohibition of placing on the market, withdrawal and/or recall from the market of the non-compliant in vitro diagnostic medical device. The economic operator shall immediately transmit to the NAMMDR proof of undertaking the measures ordered by the NAMMDR and proof of disposal of the non-compliant in vitro diagnostic medical device.

(2) The infringements mentioned in Art. 17 point b) shall be sanctioned by a fine of 10,000 to 20,000 lei, as well as by the withdrawal and/or recall of the non-compliant medical device. The economic operator and the inspector shall submit to the NAMMDR, within the established deadline, the proof of implementation of the ordered measures.

(3) The infringements mentioned in Art. 17 point c) shall be sanctioned by a fine of 10,000 to 20,000 lei, as well as by the prohibition of the use of the non-compliant medical device.

(4) The infringements mentioned in Art. 17 point d) shall be sanctioned by a fine of 5,000 to 10,000 lei, as well as the withdrawal and/or recall of the non-compliant medical device. The economic operator and the inspector shall submit to the NAMMDR, within the established deadline, the proof of implementation of the measures ordered, as well as a copy of the EU declaration of conformity of the medical device offered through distant selling of medical devices.

(5) The infringements mentioned in Art. 17 point e) shall be sanctioned by a fine of 10,000 to 20,000 lei, as well as the prohibition of the use of the non-compliant in vitro diagnostic medical device.

(6) The infringements mentioned in Art. 17 points f) and h) shall be sanctioned by a fine of 10,000 to 20,000 lei, as well as withdrawal from the market and/or prohibition of the use and introduction on the market of the non-compliant in vitro diagnostic medical device until the non-compliances are eliminated within a period established by the NAMMDR and the economic operator.

(7) The infringements mentioned in Art. 17 point g) shall be sanctioned by a fine of 5,000 to 10,000 lei, as well as by the withdrawal from the market of the non-compliant in vitro diagnostic medical device until brought into compliance.

(8) The infringements mentioned in Art. 17 point i) shall be sanctioned with a fine of 10,000 to 20,000 lei, as well as with the prohibition of placing on the market the non-compliant in vitro diagnostic medical device, withdrawal from the market until non-compliances are eliminated within a period established by the NAMMDR and the economic operator. Repeating the infringement at least 4 times during a calendar year from the application of the first sanction shall be sanctioned with a fine of 20,000 to 30,000 lei, as well as with the suspension or withdrawal of the economic operator's operating permit.

(9) The infringements mentioned in Art. 17 point j) shall be sanctioned by a fine of 10,000 to 20,000 lei, as well as by the prohibition of making available on the market and the recall of the non-compliant in vitro diagnostic medical device until non-compliances are eliminated within a period established by the NAMMDR and the economic operator. Repeating the contravention at least 4 times during a calendar year from the application of the first sanction shall be sanctioned by a fine of 20,000 to 30,000 lei, as well as by the suspension or withdrawal of the economic operator's operating permit.

(10) The infringements mentioned in Art. 17 point k) and l) shall be sanctioned by a fine of 5,000 to 10,000 lei.

(11) The infringements mentioned in Art. 17 point m) shall be sanctioned by a fine of 10,000 to 20,000 lei, as well as by the withdrawal from the market/recall and prohibition of the placing on the market of the non-compliant in vitro diagnostic medical device until non-compliances are eliminated within a period established by the NAMMDR and the economic operator.

(12) The infringements mentioned in Art. 17 point p) relating to in vitro diagnostic medical devices intended only for presentation or demonstration at trade fairs, exhibitions, demonstrations or similar events shall be sanctioned by a fine of 2,000 to 5,000 lei, as well as by withdrawal from display of the in vitro diagnostic medical device until it is brought into conformity, which shall apply to the economic operator who displayed the non-compliant device.

(13) The infringements mentioned in Art. 17 point q) are sanctioned by a fine of 10,000 to 20,000 lei, as well as by the prohibition of the use of the non-compliant in vitro diagnostic device until it is brought into compliance.

(14) The infringements mentioned in Art. 17 point r) shall be sanctioned with a fine of 2,000 to 5,000 lei.

(15) The infringements mentioned in Art. 17 points s) and v) shall be sanctioned with a fine of 10,000 to 20,000 lei, as well as with the withdrawal from the market and/or prohibition of the placing on the market of the non-compliant in vitro diagnostic medical device until non-compliances are eliminated within a period established by the NAMMDR and the economic operator.

(16) The infringements mentioned in Art. 17 points ş), t) and ţ) shall be sanctioned with a fine of 2,000 to 5,000 lei.

(17) The infringements mentioned in Art. 17 point u) shall be sanctioned with a fine of 10,000 to 20,000 lei.

(18) The infringements mentioned in Art. 17 point w) shall be sanctioned with a fine of 10,000 to 20,000 lei, as well as with the withdrawal from the market/recall and prohibition of the placing on the market of the non-compliant in vitro diagnostic medical device until non-compliances are eliminated within a period established by the NAMMDR and the manufacturer.

(19) The infringements mentioned in Art. 17 point x) shall be sanctioned with a fine of 10,000 to 20,000 lei and with discontinuation of the performance evaluation study until the non-compliances are eliminated within a period established by the NAMMDR and the sponsor.

(20) The infringements mentioned in Art. 17 point y) shall be sanctioned with a fine of 10,000 to 20,000 lei and with discontinuation of the performance evaluation until the non-compliances are eliminated within a period established by the NAMMDR and the investigator.

(21) The infringements mentioned in Art. 17 points z), aa) and ab) are sanctioned by a fine of 5,000 to 10,000 lei, as well as by the prohibition of making the medical device for in vitro diagnosis available on the market until the non-compliances are eliminated within a period established by the NAMMDR and the manufacturer.

(22) The infringements mentioned in Art. 17 points ac) and ad) shall be sanctioned by a fine of 5,000 to 10,000 lei, as well as by withdrawal from the market/recall and prohibition of the placing on the market or use of the non-compliant in vitro diagnostic medical device. The manufacturer shall immediately submit to the NAMMDR proof of implementation of the measures ordered by the NAMMDR within the established deadline.

(23) The infringements mentioned in Art. 17 point ae) are sanctioned by a fine of 5,000 lei to 10,000 lei, as well as by withdrawal from the market/recall and prohibition of the use of the non-compliant in vitro diagnostic medical device until non-compliances are eliminated within the period established by the NAMMDR and the economic operator involved.

(24) The infringements mentioned in Art. 17 point af) are sanctioned by a fine from 2,000 lei to 5,000 lei, as well as by withdrawal from the market/recall and prohibition of the use of the non-compliant in vitro diagnostic medical device until non-compliances are eliminated within the period established by the NAMMDR and the manufacturer.

(25) The infringements provided for in Art. 17 point ag) shall be sanctioned by a fine of 5,000 to 10,000 lei, as well as by withdrawal from the market/recall and prohibition of the placing on the market/use of the non-compliant in vitro diagnostic medical device. The economic operator shall immediately submit to the NAMMDR proof of the measures taken

and proof of the disposal of the non-compliant in vitro diagnostic medical device;

(26) The infringements mentioned in Art. 17 points ah) and ai) shall be sanctioned by a fine of 5,000 to 10,000 lei.

(27) The infringements mentioned in Art. 17 points aj) and ak) shall be sanctioned by a fine of 10,000 to 20,000 lei, as well as by the prohibition of placing on the market, withdrawal and/or recall and prohibition of the use of non-compliant equipment. The economic operator shall immediately submit to the NAMMDR proof of implementation of the measures ordered by the NAMMDR within the established deadline.

(28) The infringements mentioned in Art. 17 points al) shall be sanctioned by a fine of 5,000 to 10,000 lei.

Art. 19 - (1) The detection of infringements mentioned in Art. 17 and the application of sanctions provided for in Art. 18 are carried out by authorised personnel within the NAMMDR.

(1) The authorised personnel provided for in paragraph (1) may take product samples they consider necessary for the purpose of carrying out physical and laboratory checks.

(2) The authorised personnel referred to in paragraph (1) shall ensure the confidentiality of the information contained in the documents and of which they became aware during the control actions, except in situations which constitute a public health hazard, in compliance with the provisions of the General Data Protection Regulation, Law no. 190/2018, as amended, as well as with other specific regulations in the field of data protection.

(3) The provisions of Government Ordinance no. 2/2001 on the legal regime of contraventions, approved as amended and supplemented through Law no. 180/2002, as further amended and supplemented, shall apply to the infringements mentioned in Art. 17.

Art. 20 - The provisions of Art. 17 - 19 enter into force 10 days from publication of this emergency ordinance in the Official Gazette of Romania, Part I.

Art. 21 - Within 30 days from entry into force of this emergency ordinance, upon proposal of the NAMMDR, the Minister of Health shall approve the orders provided for in Art. 3 paragraph (4), Art. 4 paragraphs (2) and (3), Art. 7 paragraph (4), Art. 8 paragraph (2), Art. 9 paragraphs (2) and (3), Art. 10, Art. 12 paragraphs (1) and (2), Art. 13 paragraph (2), Art. 14 paragraph (3), Art. 15 paragraph (7), which shall be published in the Official Gazette of Romania, Part I.

Art. 22 - On entry into force of this emergency ordinance, Government Decision no. 798/2003 on establishment of conditions for placing on the market of in vitro diagnostic medical devices and their use, as amended, published in the Official Gazette of Romania, Part I, no. 555 of 1 August 2003, as further amended and supplemented, is repealed, with the exception of:

a) Art. 34 - 38, Art. 39 paragraph (2) point c), paragraphs (3) and (4), which shall be repealed 6 months after publication of the European Commission's notice in the Official Journal of the European Union on the full functioning of Eudamed, in accordance with the provisions of Art. 113 paragraph (3) point f) of the Regulation;

b) Art. 29 and Art. 39 paragraph (1) and paragraph (2) points a) and b), which shall be repealed 24 months from publication of the notice provided for in point a).

PRIME MINISTER,
NICOLAE-IONEL CIUCĂ

Countersigned:
Minister of Health,
Alexandru Rafila

On behalf of the Minister of
Economy,
Flavius Constantin Nedelcea,

Secretary of state,
On behalf of the Minister of
Foreign Affairs,
Luca-Alexandru Niculescu,
Secretary of state

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