THE CROATIAN PARLIAMENT

1930

Pursuant to Article 89 of the Constitution of the Republic of Croatia, I hereby issue the

DECISION

PROMULGATING THE ACT IMPLEMENTING REGULATION (EU) 2017/745 ON MEDICAL DEVICES AND REGULATION (EU) 2017/746 ON *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

I hereby promulgate the Act implementing Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices, passed by the Croatian Parliament at its session on 31 October 2018.

Class: 011-01/18-01/125
Reg. No: 71-06-01/1-18-2
Zagreb, 5 November 2018

The President of
the Republic of Croatia
Kolinda Grabar-Kitarović, m.p.

ACT

IMPLEMENTING REGULATION (EU) 2017/745 ON MEDICAL DEVICES AND REGULATION (EU) 2017/746 ON *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

I GENERAL PROVISIONS

Article 1

(1) This Act establishes competent authorities, procedures of competent authorities, supervision and misdemeanour provisions in relation to the implementation of European Union regulations referred to in Article 2 of this Act.

(2) The provisions of this Act shall apply to medical devices and *in vitro* diagnostic medical devices.

Article 2

This Act shall ensure the application of the following European Union regulations:

– Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and

Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)) (OJ L 117/1, 5.5.2017) – hereinafter: Regulation (EU) 2017/745

– Regulation (EU) 2017/746 of the European Parliament and the Council of the European Parliament and the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance)) (OJ L 117/1, 5.5.2017) – hereinafter: Regulation (EU) 2017/746.

Article 3

For the purposes of this Act the terms have the same meaning as the terms used in Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

Article 4

The terms used in this Act shall equally refer to common gender - masculine and feminine gender, regardless of the fact whether they have been used in the masculine or feminine form.

II COMPETENT AUTHORITIES

Article 5

For the purpose of implementing regulations referred to in Article 2 of this Act and this Act, competent authorities shall be:

– the ministry competent for health (hereinafter: the Ministry)

–Agency for Medicinal Products and Medical Devices of Croatia (hereinafter: Agency).

Article 6

For the purposes of implementing the regulations referred to in Article 2 of this Act and this Act, the Ministry shall:

– authorise clinical investigations of medical devices and substantial modifications thereof

– approve performance studies of *in vitro* diagnostic medical devices and substantial modifications thereof

– monitor and supervise the conduct of clinical investigations of medicinal devices and performance studies of *in vitro* diagnostic medical devices and take corrective actions

– decide on applications for designation of conformity assessment bodies

– notify the European Commission of the designated conformity assessment bodies

– monitor the notified bodies established in the Republic of Croatia, as well as their subsidiaries and subcontractors

– re-assess the notified body in accordance with Regulation (EU) 2017/745 and Regulation (EU) 2017/746

– decide on changes to the designation of the notified body and notify the Commission thereof

– provide its approval to the Agency to authorise the placing on the market or putting into service of a device referred to in Article 59 of Regulation (EU) 2017/745 and Article 54 of Regulation (EU) 2017/746

– may request additional information from health institutions on devices referred to in Article 5 paragraph 5 of Regulation (EU) 2017/745 and Article 5 paragraph 5 of Regulation (EU) 2017/746

– supervise the implementation of provisions of the regulations referred to in Article 2 of this Act and of this Act.

Article 7

For the purpose of implementing the provisions of the regulations referred to in Article 2 of this Act and of this Act, the Agency shall:

– verify data entered into the electronic system for registration of economic operators and assign a single registration number

– settle disputes between a manufacturer and the notified body concerned, arising from the application of the rules for classification of medical devices

– keep a register of distributors

– authorise the placing on the market or putting into service of a device referred to in Article 59 of Regulation (EU) 2017/745 and Article 54 of Regulation (EU) 2017/746 and notify the European Commission thereof

– issue a certificate of free sale in line with Article 60 of Regulation (EU) 2017/745 and Article 55 of Regulation (EU) 2017/746

– conduct vigilance of devices in line with Regulation (EU) 2017/745 and Regulation (EU) 2017/746

– may request additional information from health institutions on devices referred to in Article 5 paragraph 5 of Regulation (EU) 2017/745 and Article 5 paragraph 5 of Regulation (EU) 2017/746.

III NOTIFIED BODIES

Article 8

(1) The authority competent for the notified bodies shall be the Ministry.

(2) The Ministry shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors and subsidiaries of those bodies.

IV TRADE IN MEDICAL DEVICES AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

Article 9

(1) Prior to commencement of their activity, i.e. wholesale or retail of medical devices and *in vitro* diagnostic medical devices, distributors shall be entered into the register of distributors.

(2) The Agency shall issue a decision on entry into the register of distributors within 30 days from the day of receipt of the orderly application.

(3) Against the decision referred to in paragraph 2 of this Article no appeal is permitted but an administrative dispute may be initiated.

(4) The obligation referred to in paragraph 1 of this Article shall not apply to natural and legal persons which are authorised to carry out pharmacy activity pursuant to a separate act.

(5) The minister competent for health (hereinafter: Minister) shall, by means of an ordinance, stipulate criteria for entry into the register of distributers.

Article 10

The Agency shall, upon receiving an application for registration submitted by a manufacturer, authorised representative, or importer via the electronic system, verify data entered into the electronic system and after establishing its validity and compliance with the provisions of this Act, Regulation (EU) 2017/745 and Regulation (EU) 2017/746 assign the applicant a single registration number.

Article 11

(1) The Agency shall be competent for the settlement of disputes between the manufacturer and the notified body concerned, arising from the application of the rules for classification of medical devices.

(2) A request for dispute settlement shall be submitted to the Agency.

(3) Based on the request submitted by the manufacturer and the notified body, the Agency shall issue a decision within 30 days from the day of receipt of the orderly request.

(4) The Agency may, in the procedure referred to in paragraph 1 of this Article, request from the applicant to supplement the documentation, and in that case the deadline referred to in paragraph 3 of this Article shall be extended for 15 days.

(5) Against the decision referred to in paragraph 3 of this Article no appeal is permitted but an administrative dispute may be initiated.

Article 12

Health institutions shall, upon request, submit to competent bodies a list of all relevant additional information on medical products and *in vitro* diagnostic medical products manufactured and used within the health institution.

Article 13

(1) Single-use medical devices may be reprocessed and further used if they are in accordance with the provisions of the regulations referred to in Article 2 of this Act and of this Act.

(2) The reprocessing and further use of devices referred to in paragraph 1 of this Article which were used in a health institution and which are reprocessed and further used within the same institution shall be conducted in accordance with Article 17 paragraph 3 of Regulation (EU) 2017/745.

(3) A health institution may request reprocessing of a single-use device used within that institution from a natural or legal person with a seat established in the Republic of Croatia or other European Union Member State.

(4) Natural and legal person referred to in paragraph 3 of this Article shall, when reprocessing single-use medical devices, fulfil the requirements laid down in Article 17 paragraph 3, and in connection with the provision of Article 17 paragraph 4 of Regulation (EU) 2017/745.

(5) Health institutions shall provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with.

(6) Placement on the market of reprocessed single-use devices shall be prohibited.

Article 14

(1) The Agency may authorise, upon a duly justified request and with the approval of the Minister, the placing on the market or putting into service of those medical devices and *in vitro* diagnostic medical devices for which conformity assessment procedures have not been carried out but the use of which is in the interest of public health or patient safety or health.

(2) The authorisation referred to in paragraph 1 of this Article shall be granted or denied by a decision against which no appeal may be filed, but an administrative dispute may be initiated.

(3) The Agency shall notify the European Commission and other Member States on authorisations referred to in paragraph 1 of this Article.

Article 15

(1) The Croatian Institute for Health Insurance shall adopt a list of medicinal products covered by the compulsory health insurance which is drawn up in compliance with a separate act.

(2) The criteria for the inclusion of the medical devices in the lists of the Croatian Institute for Health Insurance shall be determined by the Minister.

V CLINICAL EVALUATION AND CLINICAL INVESTIGATIONS

Article 16

(1) The Ministry shall issue an authorisation to conduct a clinical investigation of a medical devices and performance study of an *in vitro* diagnostic medical device.

(2) The authorisation to conduct a clinical investigation of a medical device and performance study of an *in vitro* diagnostic medical device shall be granted or denied by a decision against which no appeal may be filed, but an administrative dispute may be initiated.

(3) The positive opinion of the Central Ethics Committee shall be a constituent part of the authorisation for the clinical investigation of a medical device and performance study of an *in vitro* diagnostic medical device.

(4) The criteria for the conduct of the clinical investigation of a medical device or performance study of an *in vitro* diagnostic medical device shall be regulated by the Minister by ordinance.

Article 17

A clinical investigation of a medical device or performance study of an *in vitro* diagnostic medical device may not be conducted on prisoners and persons who may be coerced into giving consent to participate in a clinical investigation or a performance study.

Article 18

(1) A clinical investigation of a medical device may take place only on the premises of a legal person which entered into a clinical trial agreement with a sponsor of a clinical investigation.

(2) A sponsor of a clinical investigation shall cover the costs of a clinical investigation referred to in paragraph 1 of this Article.

(3) The agreement referred to in paragraph 1 of this Article shall specify the total cost of the clinical investigation of the medical device and the cost to be incurred by the sponsor of the clinical investigation, including the costs of medical and other services incurred by the legal

persons referred to in paragraph 1 of this Article as well as the compensations for the investigators and subjects.

(4) The sponsor of a clinical investigation shall take out appropriate liability insurance in case of injury, death or treatment of a subject in connection with the clinical investigation.

(5) The provisions of paragraphs 1 to 4 of this Article shall appropriately apply to the conduct of a performance study of an *in vitro* diagnostic medical device.

(6) The legal person referred to in paragraph 1 of this Article shall meet the requirements laid down by the Minister by ordinance.

VI VIGILANCE

Article 19

(1) The Agency shall conduct vigilance of medical devices and in vitro diagnostic medical devices in line with the provisions of regulations referred to in Article 2 of this Act.

(2) Economic operators shall report any adverse incidents in accordance with the provisions of regulations referred to in Article 2 of this Act.

(3) Health practitioners, users and patients shall inform the Agency on any adverse incidents relating to medical devices and in vitro diagnostic medical devices.

(4) The Agency shall keep records on all adverse incidents reported by health practitioners, users and patients.

(5) The Ministry and the Agency shall take measures to encourage health practitioners, users and patients to report to competent authorities adverse incidents relating to medical devices and *in vitro* diagnostic medical devices.

VII SUPERVISION

Article 20

(1) Supervision over the implementation of the provisions of this Act and regulations adopted on the basis thereof shall be carried out by the Ministry.

(2) The Pharmaceutical Inspection of the Ministry shall carry out supervision of the market of medical devices and *in vitro* diagnostic medical devices, notified bodies and supervision over the conduct of clinical investigations of medical devices and performance studies of *in vitro* diagnostic medical devices.

Article 21

Where the pharmaceutical inspector in the process of carrying out inspections referred to in Article 20 of this Act decides to ask for verification of a medical device,

the verification costs shall be borne by the natural or legal person which placed the medical device or *in vitro* diagnostic medical device on the market or into service.

Article 22

(1) The activities of the pharmaceutical inspector may be performed by a person who holds an undergraduate and graduate university degree or an integrated undergraduate and graduate university degree in health care or any related studies, has three years of work experience on relevant jobs and has passed the state licence exam.

(2) For the performance of expert activities relating to the performance of pharmaceutical inspections for which special expertise is required, the Minister may, by means of a decision, appoint adequate experts.

(3) An expert referred to in paragraph 2 of this Article shall participate in the performance of expert activities only in the company of a pharmaceutical inspector of the Ministry.

Article 23

(1) A pharmaceutical inspector shall be issued an identity card proving his official status, identity and powers.

(2) The form and content of the identity card and the criteria for t issuing and keeping the register of issued identity cards shall be regulated by the Minister by ordinance.

Article 24

Where during the inspection the pharmaceutical inspector finds that an infringement has been committed that constitutes a misdemeanour offence or a criminal offence, he shall without delay, within a deadline not exceeding 15 days from the day on which the inspection is completed, file an indictment or charges before the competent authority.

Article 25

Legal and natural persons shall ensure the undisturbed performance of the inspection by the pharmaceutical inspector and at his request make available the required quantity of samples for verification as well as provide other necessary data and information.

Article 26

If during the inspection a pharmaceutical inspector encounters physical resistance, he may request police assistance.

Article 27

(1) In carrying out inspections the pharmaceutical inspector shall act in line with data confidentiality regulations.

(2) The legal and natural person shall inform the pharmaceutical inspector of the data they have designated as confidential.

VIII PROCEDURAL PROVISIONS

Article 28

Remuneration for activities laid down in the regulations referred to in Article 2 of this Act shall be set by the Minister by ordinance.

Article 29

(1) The procedures laid down in this Act fall under the scope of the act governing general administrative procedure.

(2) Against an act issued by the competent authority no appeal may be filed, but administrative dispute may be initiated.

Article 30

(1) Data and documents used for implementing the regulations referred to in Article 2 of this Act, which are intended to be used by patients and lay persons, shall be in the Croatian language.

(2) Data and documents used for implementing the regulations referred to in Article 2 of this Act, which are intended to be used by competent authorities or exclusively for the performance of healthcare activity, may be in the Croatian and/or English language.

(3) The certificates issued by notified bodies in accordance with the regulations referred to in Article 2 of this Act shall be at least in Croatian.

(4) Competent authorities shall draw up documents related to the implementation of the regulations referred to in Article 2 of this Act in the Croatian language.

IX MISDEMEANOUR PROVISIONS

Article 31

(1) A misdemeanour fine in the amount ranging from HRK 100,000.00 to 700,000.00 shall be imposed on a legal person if they:

1. acting as an economic operator, place on the market or put into service a medical device in contravention of Regulation (EU) 2017/745 and Regulation (EU) 2017/746, as well as if that device is not duly supplied and properly installed, maintained and used in accordance with its intended purpose (Article 5 paragraph 1 of Regulation (EU) 2017/745 and Article 5 paragraph 1 of Regulation (EU) 2017/746)

2. acting as an economic operator, place on the market or put into service a medical device or *in vitro* diagnostic medical device which fails to meet the general safety and performance

requirements set out in Annex I of Article 5 paragraph 2 of Regulation (EU) 2017/745 and Annex I of Article 5 paragraph 2 of Regulation 2017/746

3. acting as a manufacturer, place on the market or put into service a medical device or *in vitro* diagnostic medical device which has not been designed and manufactured in accordance with the requirements of Regulation (EU) 2017/745 (Article 10 paragraph 1 of Regulation (EU) 2017/745 and Article 10 paragraph 1 of Regulation (EU) 2017/746)

4. acting as a manufacturer, fail to establish, document, implement and maintain a system for risk management (Article 10 paragraph 2 of Regulation (EU) 2017/745 and Article 10 paragraph 2 of Regulation (EU) 2017/746)

5. acting as a manufacturer, fail to conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV to Regulation (EU) 2017/745, including post-market surveillance (Article 10 paragraph 3 of Regulation (EU) 2017/745)

6. acting as a manufacturer, fail to conduct a performance evaluation in accordance with the requirements set out in Article 56 and Annex XIII to Regulation (EU) 2017/746, including post-market surveillance (Article 10 paragraph 3 of Regulation (EU) 2017/746)

7. acting as an importer, fail to inform the competent authority, prior to placing on the market of a medical device or *in vitro* diagnostic medical device, if they consider or have reason to believe that the device presents a serious risk or is a falsified device (Article 13 paragraph 2 of Regulation (EU) 2017/745 and Article 13 paragraph 2 of Regulation (EU) 2017/746)

8. acting as an importer, fail to indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted (Article 13 paragraph 3 of Regulation (EU) 2017/745 and Article 13 paragraph 3 of Regulation (EU) 2017/746)

9. as an importer fails to ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I to Regulation (EU) 2017/745 and Annex I to Regulation (EU) 2017/746 and fail to comply with the conditions set by the manufacturer (Article 13 paragraph 5 of Regulation (EU) 2017/745 and Article 13 paragraph 5 of Regulation (EU) 2017/746)

10. acting as an importer, fail to inform the manufacturer and its authorised representative if they consider or have reason to believe that a medical device or in vitro diagnostic medical device which they have placed on the market is not in conformity with Regulation (EU) 2017/745 and Regulation (EU) 2017/746, and if they fail to cooperate with the manufacturer, the manufacturer's authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it and, if the device presents a serious risk, fail to immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 56 of Regulation (EU) 2017/745, i.e.

Article 51 of Regulation (EU) 2017/746 (Article 13 paragraph 7 of Regulation (EU) 2017/745 and Article 13 paragraph 7 of Regulation (EU) 2017/746)

11. acting as an importer, fail to immediately forward to the manufacturer and its authorised representative complaints or reports submitted by healthcare professionals, patients or users about suspected incidents related to a medical device or *in vitro* diagnostic medical device which they have placed on the market (Article 13 paragraph 8 of Regulation (EU) 2017/745 and Article 13 paragraph 8 of Regulation (EU) 2017/746)

12. acting as a distributor, place on the market a medical device or *in vitro* diagnostic device which is not in conformity with the requirements of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 and do not inform thereof the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. (Article 14 paragraph 2 of Regulation (EU) 2017/745 and Article 14 paragraph 2 of Regulation (EU) 2017/746)

13. acting as a distributor, prior to placing on the market a medical device or in vitro diagnostic device do not inform the competent authority of the Member State in which they are established if they consider or have reason to believe that the device presents a serious risk or is a falsified device (Article 14 paragraph 2 of Regulation (EU) 2017/745 and Article 14 paragraph 2 of Regulation (EU) 2017/746)

14. acting as a distributor, while the device is under their responsibility, do not ensure that storage or transport conditions comply with the conditions set by the manufacturer (Article 14 paragraph 3 of Regulation (EU) 2017/745 and Article 14 paragraph 3 of Regulation (EU) 2017/746)

15. acting as a distributor, do not inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer if they consider or have reason to believe that a device which they have made available on the market is not in conformity with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 and do not ensure, in co-operation with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken; and if they do not immediately inform the competent authorities of the Member States in which they made the device available that they consider or have reason to believe that the device presents a serious risk (Article 14 paragraph 4 of Regulation (EU) 2017/745 and Article 14 paragraph 4 of Regulation (EU) 2017/746)

16. acting as a distributor, do not immediately forward to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, complaints or reports received from healthcare professionals, patients or users about suspected incidents related to a medical device or *in vitro* diagnostic medical device they have made available and do not keep a register of complaints, of non-conforming devices and of recalls and withdrawals (Article 14 paragraph 5 of Regulation (EU) 2017/745 and Article 14 paragraph 5 of Regulation (EU) 2017/746)

17. acting as a distributor or importer, while carrying out any of the activities mentioned in Article 16 paragraph 2 points (a) and (b) of Regulation (EU) 2017/745 and in Article 16 paragraphs(a) and (b) of Regulation (EU) 2017/746, do not ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in paragraph 2 points (a) and (b) of Regulation (EU) 2017/745 and paragraphs (a) and (b) of Regulation (EU) 2017/746 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy (Article 16 paragraph 3 of Regulation (EU) 2017/745 and Article 16 paragraph 3 of Regulation (EU) 2017/746)

18. place on the market reprocessed single-use devices (Article 13 paragraph 6 of this Act)

19. do not provide patients information on the use of reprocessed medical products as well as any other relevant information on the reprocessed devices that patients are treated with (Article 13 paragraph 5 of this Act and Article 17 paragraph 3 of Regulation (EU) 2017/745)

20. acting as a manufacturer of an implantable device, do not provide together with the implant card of the device information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer (Article 18 paragraph 1 point (a) of Regulation (EU) 2017/745)

21. acting as a manufacturer of an implantable device, do not provide together with the implant card of the device any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions (Article 18 paragraph 1 point (b) of Regulation (EU) 2017/745)

22. acting as a manufacturer of an implantable device, do not provide together with the implant card of the device any information about the expected lifetime of the device and any necessary follow-up (Article 18 paragraph 1 point (c) of Regulation (EU) 2017/745)

23. acting as a manufacturer of an implantable device, do not provide together with the implant card of the device any other information to ensure safe use of the device by the patient, including the information in point (u) of Section 23.4 of Annex I of Regulation (EU) 2017/745 (Article 18 paragraph 1 point (d) of Regulation (EU) 2017/745)

24. do not ensure any patients who have been implanted with a medical device rapid access to that information, together with the implant card, which shall bear their identity (Article 18 paragraph 2. Regulation (EU) 2017/745)

25. do not label devices, other than custom-made or investigational devices, with the CE marking of conformity (Article 20 paragraph 1 of Regulation (EU) 2017/745)

26. do not label devices, other than devices for performance studies, with the CE marking of conformity (Article 18 paragraph 1 of Regulation (EU) 2017/746)

27. acting as a manufacturer, do not assign a UDI to the medical device before placing a device, other than a custom-made device, on the market, and if applicable, to all higher levels of packaging (Article 27 paragraph 3 of Regulation (EU) 2017/745)

28. acting as a manufacturer, do not assign a UDI to the *in vitro* diagnostic medical device before placing a device, other than a device for performance study, on the market, the manufacturer and, if applicable, to all higher levels of packaging (Article 24 paragraph 3 of Regulation (EU) 2017/746)

29. acting as a manufacturer, do not assign a Basic UDI-DI to the device before placing a device, other than a custom-made device and do not provide it to the UDI database (Article 29 paragraph 1 of Regulation (EU) 2017/745)

30. acting as a manufacturer, do not assign a Basic UDI-DI to an *in vitro* diagnostic medical device before placing a device on the market and do not provide it to the UDI database (Article 26 paragraph 1 of Regulation (EU) 2017/746)

31. acting as a manufacturer, do not shall draw up a summary of safety and clinical performance for implantable devices and for class III devices, other than custom-made or investigational devices (Article 32 paragraph 1 of Regulation (EU) 2017/745)

32. acting as a manufacturer, do not draw up a summary of safety and performance for class C and D *in vitro* diagnostic medical devices, other than devices for performance studies (Article 29 paragraph 1 of Regulation (EU) 2017/746)

33. acting as a notified body, do not verify whether the subcontractor or the subsidiary to which they have subcontracted specific tasks connected with conformity assessment meets the applicable requirements set out in Annex VII of Regulation (EU) 2017/745 and in Annex VII of Regulation (EU) 2017/746 and do not inform the Ministry and do not make publicly available a list of their subsidiaries (Article 37 paragraphs 1 and 3 of Regulation (EU) 2017/745 and Article 33 paragraphs 1 and 3 of Regulation (EU) 2017/746)

34. acting as a manufacturer, do not undertake an assessment of the conformity of the medical device or *in vitro* diagnostic medical device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI prior to placing a device on the market referred to in Article 52 paragraph 1 of Regulation (EU) 2017/745 and in Annexes IX – XI from Article 48 paragraph 1 of Regulation (EU) 2017/746

35. acting as a sponsor of a clinical investigation, conduct a clinical investigation without having met the conditions referred to in Article 62 paragraph 4 of Regulation (EU) 2017/745

36. acting as a sponsor of a performance study, conduct a sponsor study without having met the conditions referred to in Article 58 paragraph 5 of Regulation (EU) 2017/746

37. acting as a sponsor of a clinical investigation, conduct a clinical investigation on incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, without having met the conditions referred to in Article 62 paragraph 4 and Article 64 paragraph 1 of Regulation (EU) 2017/745

38. acting as a sponsor of a performance study, conduct a performance study on incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, without having met the conditions referred to in Article 58 paragraph 5 and Article 60 paragraph 1 of Regulation (EU) 2017/746

39. acting as a sponsor of a clinical investigation, conduct a clinical investigation on minors, without having met the conditions referred to in Article 62 paragraph 4 and Article 65 of Regulation (EU) 2017/745

40. acting as a sponsor of a performance study, conduct a performance study on minors, without having met the conditions referred to in Article 58 paragraph 5 and Article 61 of Regulation (EU) 2017/746

41. acting as a sponsor of a clinical investigation, conduct a clinical investigation on pregnant women or breastfeeding women, without having met the conditions referred to in Article 62 paragraph 4 and Article 66 of Regulation (EU) 2017/745

42. acting as a sponsor of a performance study, conduct a performance study on pregnant women or breastfeeding women, without having met the conditions referred to in Article 58 paragraph 5 and Article 62 of Regulation (EU) 2017/746

43. acting as a sponsor of a clinical investigation or as a sponsor of a performance study, conduct a clinical investigation or a performance study on the persons referred to in Article 17 of this Act

44. acting as a sponsor of a clinical investigation, have not informed the Ministry that they have temporarily halted a clinical investigation or have terminated a clinical investigation early, within 15 days through an electronic system and have not informed the Ministry that they have temporarily halted a clinical investigation or have terminated a clinical investigation early on safety grounds, within 24 hours (Article 77 paragraph 1 of Regulation (EU) 2017/745)

45. acting as a sponsor of a performance study, do not inform the Ministry that they have temporarily halted a performance study or have terminated a performance study early, within 15 days through an electronic system and do not inform the Ministry that they have temporarily halted a performance study or have terminated a performance study early on safety grounds, within 24 hours (Article 73 paragraph 1 of Regulation (EU) 2017/746)

46. acting as a sponsor of a clinical investigation, do not notify the Ministry of the end of that clinical investigation within 15 days of the end of the clinical investigation in the Republic of Croatia (Article 77 paragraph 3 of Regulation (EU) 2017/745)

47. acting as a sponsor of a performance study, do not notify the Ministry of the end of that performance study within 15 days of the end of the performance study in the Republic of Croatia (Article 73 paragraph 3 of Regulation (EU) 2017/746)

48. acting as a sponsor of a clinical investigation, do not submit to the Ministry a clinical investigation report within one year of the end of the clinical investigation or within three months of the early termination or temporary halt (Article 77 paragraph 5 of Regulation (EU) 2017/745)

49. acting as a sponsor of a performance study, do not submit to the Ministry a performance study report within one year of the end of the performance study or within three months of the early termination or temporary halt (Article 73 paragraph 5 of Regulation (EU) 2017/746)

50. acting as a sponsor of a clinical investigation, do not report, without delay to competent authorities by means of an electronic system on the events referred to in Article 80 paragraph 2 of Regulation (EU) 2017/745

51. acting as a sponsor of a performance study, do not report, without delay to competent authorities by means of an electronic system on the events referred Article 76 paragraph 2 of Regulation (EU) 2017/746

52. acting a manufacturer of class I devices or *in vitro* diagnostic medical devices of Class A and B, do not prepare a post-market surveillance report and do not make the report available upon request of the notified body and the competent authority (Article 85 of Regulation (EU) 2017/745 and Article 80 of Regulation (EU) 2017/746)

53. acting as a manufacturer of medical devices, other than investigational devices, and *in vitro* diagnostic medical devices, other than performance study products, do not report to the Agency of any serious incident and field safety corrective actions (Article 87 Regulation (EU) 2017/745 and Article 82 of Regulation (EU) 2017/746)

54. acting as a manufacturer of a medical device and *in vitro* diagnostic medical device do not ensure that information about the field safety corrective action taken is brought without delay to the attention of users of the device in question by means of a field safety notice (Article 89 paragraph 8 of Regulation (EU) 2017/745 and Article 84 paragraph 8 of Regulation (EU) 2017/746.

(2) A fine ranging from HRK 70,000.00 to 300,000.00 shall also be imposed on a natural person craftsman and a person performing another self-employed activity that committed the misdemeanour referred to in paragraph 1 of this Article in relation to performing their craft or other self-employed activity.

(3) For the misdemeanour referred to in paragraph 1 of this Article a responsible person within a legal person shall also be fined in an amount ranging from HRK 7000.00 to 10,000.00.

Article 32

(1) A misdemeanour fine ranging from HRK 50,000.00 to 200,000.00 shall be imposed on a legal person if they:

1. upon request by a competent authority, do not make available a copy of the EU declaration of conformity of the medical device or *in vitro* diagnostic medical device (Article 6 paragraph 3 of Regulation (EU) 2017/745 and Article 6 paragraph 3 of Regulation (EU) 2017/746)

2. in the labelling, instructions for use, making available, putting into service and advertising of a medical device or *in vitro* diagnostic medical device, use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by ascribing functions and properties to the device which the device does not have (Article 7 point (a) of Regulation (EU) 2017/745 and Article 7 point (a) of Regulation (EU) 2017/746)

3. in the labelling, instructions for use, making available, putting into service and advertising of a medical device or in vitro diagnostic medical device, use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have (Article 7 point (b) of Regulation (EU) 2017/745 and Article 7 point (b) of Regulation (EU) 2017/746)

4. in the labelling, instructions for use, making available, putting into service and advertising of a medical device or in vitro diagnostic medical device, use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose (Article 7 point (c) of Regulation (EU) 2017/745 and Article 7 point (c) of Regulation (EU) 2017/746)

5. in the labelling, instructions for use, making available, putting into service and advertising of a medical device or in vitro diagnostic medical device, use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out (Article 7 point (d) of Regulation (EU) 2017/745 and Article 7 point (d) of Regulation (EU) 2017/746)

6. acting as a manufacturer of custom-made devices, do not draw up, keep up to date and keep available for competent authorities documentation in accordance with Section 2 of Annex XIII of Regulation (EU) 2017/745 (Article 10 paragraph 5 of Regulation (EU) 2017/745)

7. acting as a manufacturer, do not keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments

and supplements, issued in accordance with Article 51, available for the competent authorities (Article 10 paragraph 7 of Regulation (EU) 2017/746)

8. as a manufacturer, do not ensure that along with the medical device all the information stated in Annex I Section 23 of Regulation (EU) 2017/745 is provided to the user or patient in the Croatian language (Article 10 paragraph 11 of Regulation (EU) 2017/745 and Article 30 of this Act)

9. as a manufacturer, do not ensure that along with the *in vitro* diagnostic medical device all the information stated in Annex I Section 17 of Regulation (EU) 2017/746 is provided to the user or patient in the Croatian language (Article 10 paragraph 10 of Regulation (EU) 2017/746 and Article 30 of this Act)

10. acting as an importer, do not indicate on the medical device or on the *in vitro* diagnostic medical device or its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established (Article 13 paragraph 3 of Regulation (EU) 2017/745 and Article 13 paragraph 3 of Regulation (EU) 2017/746)

11. acting as a distributer or importer, do not inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available, at least 28 days prior to making the relabelled or repackaged medical device or on the *in vitro* diagnostic medical device available on the market, and upon request, do not provide the manufacturer and the competent authority with a sample or mock-up of the relabelled or repackaged device (Article 16 paragraph 4 of Regulation (EU) 2017/745 and Article 16 paragraph 4 of Regulation (EU) 2017/746)

12. acting as a manufacturer, do not continuously update the EU declaration of conformity (Article 19 paragraph 1 of Regulation (EU) 2017/745)

13. acting as a manufacturer, do not continuously update the EU declaration of conformity. (Article 17 paragraph 1 of Regulation (EU) 2017/746)

14. acting as a manufacturer of a custom-made medical device or their authorised representative, do not make available to the patient or user the statement from Annex XIII Section 1 of Regulation (EU) 2017/745 (Article 21 paragraph 2 of Regulation (EU) 2017/745)

15. acting as a notified body, do not publish a list of all their subsidiaries (Article 37 paragraph 3 of Regulation (EU) 2017/745 and Article 33 paragraph 3 of Regulation (EU) 2017/746)

16. acting as a notified body, do not update documentation whenever relevant changes occur in relation to the medical device or *in vitro* diagnostic medical device in compliance with Annex VII of Regulation (EU) 2017/745 i Regulation (EU) 2017/746 (Article 38 paragraph 3 of Regulation (EU) 2017/745 and Article 34 paragraph 3 of Regulation (EU) 2017/746)

17. acting as a notified body, do not inform the Ministry without delay and at the latest within 15 days of all relevant changes which may affect their compliance with the requirements set out in Annex VII of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (Article 44 paragraph 1 of Regulation (EU) 2017/745 and Article 40 paragraph 1 of Regulation (EU) 2017/746).

(2) A fine ranging from HRK 10,000.00 to 60,000.00 shall also be imposed on a natural person craftsman and a person performing another self-employed activity that committed the misdemeanour referred to in paragraph 1 of this Article in relation to performing their craft or other self-employed activity.

(3) For the misdemeanour referred to in paragraph 1 of this Article a responsible person within a legal person shall also be fined in an amount ranging from HRK 5000.00 to 8000.00.

X TRANSITIONAL AND FINAL PROVISIONS

Article 33

The Ordinances referred to in Article 9 paragraph 5, Article 15 paragraph 2, Article 16 paragraph 4, Article 18 paragraph 6 and Article 23 paragraph 2 of this Act and the decision referred to in Article 28 of this Act shall be issued by the Minister within 18 months from the day of entry into force of this Act.

Article 34

This Act shall enter into force on the eighth day from the day of its publication in the Official Gazette.

Class: 022-03/18-01/104

Zagreb, 31 November 2018

THE CROATIAN PARLIAMENT

The President of the
Croatian Parliament
Gordan Jandroković, m.p.