REGULATION ON CLINICAL TRIALS OF MEDICAL DEVICES

SECTION ONE Introductory Provisions Objective

ARTICLE 1- (1) The objective of this Regulation is to regulate the procedures and principles regarding post-market studies and clinical trials of medical devices, as well as the protection of the rights of the volunteers participating in such trials, within the framework of the international agreements to which Türkiye is a party, European Union standards, and good clinical practice. Scope

ARTICLE 2- (1) This Regulation covers post-market studies and clinical trials of medical devices, the sites where such trials may be conducted, and the natural or legal persons who will carry out such trials. (2) Retrospective studies and performance evaluation studies conducted with in vitro diagnostic medical devices are outside the scope of this Regulation. Legal Basis

ARTICLE 3- (1) This Regulation has been prepared based on Article Add-10 of the Fundamental Law on Health Services No. 3359 dated 7/5/1987, and Articles 508 and 796 of the Presidential Decree No. 4 on the Organization of Institutions and Organizations Affiliated with, Related to, or Associated with Ministries and Other Institutions and Organizations. Definitions

ARTICLE 4- (1) In this Regulation; a) Multicentre clinical trial: a clinical trial conducted in more than one centre according to a single protocol, and which therefore has more than one principal investigator, b) Inspection: the activities of examination by the Agency of the sites where clinical trials are conducted, the centres belonging to the sponsor, legal representative, if any, and the contract research organisation, the documents and records of the trial, the quality assurance arrangements, and other institutions, boards and organisations related to the trial, including ethics committees, with respect to their compliance with this Regulation and other relevant legislation, c) Date of full functionality of EUDAMED: the date six months after the date of publication of the notice that EUDAMED, the European database on medical devices established by the Commission pursuant to Article 33 of the Regulation on Medical Devices published in the Official Gazette No. 31499 duplicated dated 2/6/2021, is fully functional and meets its functional specifications in the Official Journal of the European Union, ç) Administrative responsible person: in a multicentre trial, a physician or dentist who has completed specialty or doctoral training and is administratively responsible for the conduct of the trial, d) Good clinical practice: the rules to be complied with by the parties involved in the trial, covering arrangements concerning matters such as the design, conduct, monitoring, budgeting, evaluation and reporting of trials in order to ensure that trials are conducted in accordance with international scientific and ethical standards, the protection of all rights and physical integrity of the volunteer, ensuring the reliability of the trial data and maintaining their confidentiality, e) Monitor: the person appointed by the sponsor, independent of the trial site, in order to verify that the trial is conducted in accordance with the clinical trial plan, the principles of good clinical practice and the legislative requirements, f) Coordinator: in a multicentre clinical trial, the person responsible for ensuring coordination between the investigators of the centres and the ethics committee, the sponsor, the legal representative, if any, and, where necessary, between them and the Agency, g) Post-market study: studies conducted on volunteers for the purpose of collecting performance or safety data of a device, provided that the device is used in accordance with the intended purposes determined by the manufacturer of devices placed on the market with a CE marking affixed thereto in compliance with the Regulation on Medical Devices, ğ) Retrospective study: studies in which retrospective data are collected, h) Contract research organisation: an independent organisation operating in accordance with the principles of good clinical practice, to which the sponsor transfers all or part of its duties and authorities related to the clinical trial by means of a written contract, ı) Regulation on Medical Devices: the Regulation on Medical Devices published in the Official Gazette No. 31499 duplicated dated 2/6/2021, (2) The definitions set forth in Article 3 of the Regulation on Medical Devices shall also apply to this Regulation.

SECTION TWO General Principles of the Trial General principles regarding clinical trials

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ARTICLE 5- (1) With respect to clinical trials, Articles 62 to 80 of the Medical Devices Regulation shall apply. With respect to these Articles, action shall be taken in accordance with the dates of entry into force set forth in Article 111 of the Medical Devices Regulation. The following provisions shall apply together with the relevant Articles of the Medical Devices Regulation. (2) In accordance with the international standards specified in paragraph (a) of the third paragraph of Article 62 of the Medical Devices Regulation: a) The investigational device must, as a priority, have been studied in a non-human testing environment or on a sufficient number of experimental animals. b) The scientific data obtained as a result of experiments conducted in a non-human testing environment or on animals must provide sufficient evidence for the conduct of clinical trials of the device(s) in terms of achieving the intended objective of the trial. c) No research may be conducted aimed at altering the genetic structure of the germ cells of a participant (volunteer). (3) The Clinical Trial Ethics Committees, whose structure, working procedures and principles are set forth in the Regulation on Clinical Trials of Medicinal and Biological Products published in the Official Gazette No. 28617 dated 13/4/2013 and which have been approved by the Agency, are authorized to carry out the scientific and ethical review specified in paragraph (c) of the third paragraph of Article 62 of the Medical Devices Regulation. The Clinical Trial Ethics Committees are responsible, to the extent of their duties and powers, for the review, monitoring and follow-up of post-market studies and medical device clinical trials. (4) Pursuant to subparagraph (ı) of the fourth paragraph of Article 62 of the Medical Devices Regulation, no persuasive inducement or financial offer may be made to a participant (volunteer) or his/her legal guardian for the participation of participants (volunteers) in the trial or for ensuring the continuation of such participation. However, the expenses that will arise from the participation of participants (volunteers) in the trial and the loss of income incurred by healthy participants (volunteers) due to loss of working days shall be specified in the trial budget and may be covered from this budget. (5) Pursuant to the sixth paragraph of Article 62 of the Medical Devices Regulation, trials shall be conducted by a team of investigators appropriate to the nature of the trial, under the chairmanship of the principal investigator. A physician or dentist from within the trial team who has completed specialty or doctoral training in the field related to the subject of the trial shall be designated as the principal investigator. (6) Pursuant to the seventh paragraph of Article 62 of the Medical Devices Regulation, trials may preferably be conducted in places designed for clinical trials at university healthcare application and research centers, approved research and development centers affiliated with universities, and Ministry of Health training and research hospitals, which possess personnel, equipment and laboratory facilities suitable for ensuring the safety of the persons on whom the trial is to be conducted, for the sound conduct, follow-up and, where necessary, emergency intervention of the trial, and appropriate to the nature of the trial. Healthcare institutions and organizations possessing the specified qualities may also be included in clinical trials conducted at these centers and hospitals, provided that this is under the coordination or administrative responsibility of these centers and hospitals where necessary. Based on good clinical practice, the places where clinical trials are to be conducted shall, as a minimum, have: a) The necessary and sufficient personnel and equipment according to the nature of the trial, b) The premises and facilities necessary for the storage and distribution of the product according to the nature of the device for research purposes, c) The facilities and equipment to provide appropriate care services for the participant (volunteer), including situations that may require emergency intervention, ç) Sufficient facilities and equipment to enable the transfer of the participant (volunteer) to a more advanced healthcare institution or organization when necessary, d) Sufficient facilities and equipment to retain the information and documents pertaining to the clinical trial and to the participants (volunteers) after the completion of the trial. (7) Pursuant to Article 63 of the Medical Devices Regulation, in cases where the participant (volunteer) is unable to give his/her informed consent, the person authorized to give approval for the participation of the participant (volunteer) in the trial under the legislation in force shall be deemed the authorized guardian. (8) Pursuant to paragraph (c) of the second paragraph of Article 63 of the Medical Devices Regulation, the

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preliminary interview regarding the informed consent form (ICF) shall be conducted by the principal investigator or by a physician or dentist who is part of the trial team and has been authorized by the principal investigator. (9) Pursuant to Article 69 of the Medical Devices Regulation, insurance shall not be required, provided that the ethics committee deems it appropriate according to the benefit-risk ratio, in medical device clinical trials conducted with devices bearing the CE mark and in accordance with the intended use specified by the manufacturer of the medical device, for the purpose of securing participants (volunteers) against damages that may arise from the clinical trial; however, in all other medical device clinical trials, participants (volunteers) shall be insured. A proposed insurance may be submitted in applications to the ethics committee and the Agency, provided that the final insurance is submitted before the initiation of the trial. (10) In multicenter trials, a coordinator shall be selected by the sponsor from among the principal investigators. In multinational and multicenter trials, a coordinator shall be selected by the sponsor from among the principal investigators in Turkey as the country coordinator. The trial site where the coordinator is located shall be deemed the coordinating center. The coordinator must be selected from among the principal investigators of the centers that may serve as coordinators as specified in the sixth paragraph.

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Clinical Trials in Vulnerable Populations

ARTICLE 6- (1) With regard to clinical trials in vulnerable populations, the provisions of Articles 64 to 68 of the Medical Devices Regulation shall apply together with the provisions laid down in this Article. (2) Pursuant to the seventh paragraph of Article 63 of the Medical Devices Regulation, for children to participate in trials, if the child has the capacity to express consent, the written approval of the mother and father, or of the guardian if the child is under guardianship, in accordance with Article 63 of the said Regulation, shall be obtained in addition to the child's own consent. (3) In trials involving the incapacitated persons specified in Article 64 of the Medical Devices Regulation, the ethics committee shall be informed by a physician who has acquired expertise in the field related to the trial, regarding the clinical, ethical, psychological and social problems related to the trial, and the protocol shall be evaluated accordingly. (4) In trials involving children as specified in Article 65 of the Medical Devices Regulation, the ethics committee shall be informed by a physician who is a specialist in pediatrics, regarding the clinical, ethical, psychological and social problems related to the trial, and the protocol shall be evaluated accordingly. The ethics committee may not approve such a trial without a positive opinion from a physician who is a specialist in pediatrics regarding the conduct of the trial on children. (5) In trials involving pregnant or breastfeeding women as specified in Article 66 of the Medical Devices Regulation, the ethics committee shall be informed, with regard to the health of the pregnant or breastfeeding woman or of the embryo, foetus or child after birth, by a physician who has acquired expertise in the field related to the trial, regarding the clinical, ethical, psychological and social problems, and the protocol shall be evaluated accordingly. (6) The additional safeguards specified in Article 67 of the Medical Devices Regulation may also apply to persons with limited or diminished autonomy who are situated within a particular hierarchical structure or whose capacity to protect themselves has not yet developed, has diminished or has been entirely lost due to economic, social and medical reasons. (7) In trials in emergency situations as specified in Article 68 of the Medical Devices Regulation, the ethics committee shall be informed by a physician who has acquired expertise in the field related to the trial, regarding the clinical, ethical, psychological and social problems related to the trial, and the protocol shall be evaluated accordingly. (8) Where the subject matter of the trial directly concerns persons who are incapable of giving consent, or where a condition can only be studied in persons incapable of giving consent, or where all existing treatment options related to the disease of persons incapable of giving consent have been exhausted, a trial may be permitted to be conducted on persons incapable of giving consent, provided that the trial carries no foreseeable risk to the health of such persons and there is a general medical opinion that the trial will provide a direct benefit to them, within the framework of Article 5, the fourth paragraph of Article 62 of the Medical Devices Regulation, and the following: a) There must be a general medical opinion that the trial carries no known risk to persons incapable of giving consent. b) The legal guardians, if any, of persons incapable of giving consent shall be informed in accordance with Article 63 of the Medical Devices Regulation and their written approval shall be obtained. c) If persons incapable of giving consent regain the capacity to assess the information provided to them and to form an opinion on this matter, they shall be immediately withdrawn from the trial if they refuse to participate or wish to withdraw from the trial at any stage. ç) The ethics committee shall be informed by a physician who has acquired expertise in the field related to the trial, regarding the clinical, ethical, psychological and social problems related to the trial, and the protocol shall be evaluated accordingly. d) Where the written approval of the legal guardians of persons incapable of giving consent cannot be obtained because such guardians cannot be reached, persons incapable of giving consent may be included in the trial under the responsibility of the principal investigator or an investigator who is a physician, provided that, together with the provisions of the first paragraph, the following conditions are met: 1) The ethics committee has evaluated in advance whether the proposed trial protocol or other documents adequately address the ethical aspects of the trial in question, 2) In cases such as cardiac arrest, head trauma, central nervous system infections and intracranial haemorrhages,

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which develop suddenly and require immediate intervention by the physician and where all existing treatment options have been exhausted, there is a general medical opinion that the trial will provide a direct benefit to persons incapable of giving consent.

SECTION THREE Commencement and Conduct of Trials Clinical trial application

ARTICLE 7- (1) Until the date of full functionality of EUDAMED, the following provisions shall apply to clinical trial applications: a) The sponsor of the clinical trial shall submit an application through the electronic application system of the Agency, together with the documentation referred to in Section II of Annex XV to the Medical Devices Regulation. b) It is essential that the application be duly made, that there be no deficiency in the information and documents required for the application, and that the application be reviewed and concluded by the Agency within twenty working days. c) Clinical trials may not commence without the authorisation of the Agency. (2) As of the date of full functionality of EUDAMED, Article 70 of the Medical Devices Regulation shall apply.

Evaluation of the clinical trial application

ARTICLE 8- (1) The Agency shall evaluate clinical trial applications in line with the matters set out in Article 71 of the Medical Devices Regulation. The reference in paragraph four, subparagraph (a) of the said Article to the completeness of the application shall also be deemed to be a reference to subparagraphs (a) and (b) of the first paragraph of Article 7 of this Regulation. (2) In multicentre clinical trials, a single ethics committee decision shall be sufficient. In applications to be submitted to the Agency, the ethics committee decision shall be presented as part of the application. (3) When applying to the Agency, previous negative ethics committee decisions shall be presented to the Agency at the time of application, even if approval has been obtained from the same ethics committee for the trial concerned. Conduct of the clinical trial

ARTICLE 9- (1) The provisions of Article 72 of the Medical Devices Regulation shall apply to the conduct of the clinical trial. (2) In order to keep the identity of the volunteers participating in the trial confidential, when any adverse event or trial-related data is reported by the principal investigator or other investigators, the volunteer code assigned to each volunteer shall be used instead of the volunteer's name and identifying information. (3) Personal data of volunteers may under no circumstances be made public. Post-market studies

ARTICLE 10- (1) Until the date of full functionality of EUDAMED, the following provisions shall apply to post-market studies: a) Articles 62 to 69 of the Medical Devices Regulation and paragraphs three to ten of Article 5 of this Regulation, b) Article 6, the first paragraph of Article 7, Articles 8 and 9, the first paragraph of Article 11, the first paragraph of Article 12, the first paragraph of Article 13, and paragraphs one and two of Article 14, (2) As of the date of full functionality of EUDAMED, Article 74 of the Medical Devices Regulation shall apply. Substantial modifications in clinical trials

ARTICLE 11- (1) Until the date of EUDAMED functionality, in a clinical trial, for changes that are likely to have a substantial impact on the safety, health or rights of the volunteers or on the robustness or reliability of the clinical data generated by the trial (substantial changes); a) The sponsor of the clinical trial applies, together with the nature of and reasons for the changes to be made, through the Agency's electronic application system. Up-to-date versions of the documentation referred to in Section II of Annex XV of the Medical Device Regulation shall be submitted as part of this application. Changes in the relevant documents must be clearly identifiable. b) Provided that the application is duly made and there is no deficiency in the information and documents required to be submitted, it is essential that the application be reviewed and concluded by the Agency within thirty working days. c) The Agency evaluates substantial change applications in line with the matters set out in Article 8 of this Regulation. ç) Substantial changes may not be implemented without the Agency's authorisation. (2) As of the date of EUDAMED functionality, Article 75 of the Medical Device Regulation shall apply.

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Corrective measures

ARTICLE 12- (1) Until the date of EUDAMED functionality, the first and second paragraphs of Article 76 of the Medical Device Regulation shall apply to corrective measures to be taken in trials. (2) As of the date of EUDAMED functionality, Article 76 of the Medical Device Regulation shall apply.

Information from the sponsor where a clinical trial is concluded, temporarily suspended or terminated early

ARTICLE 13- (1) Until the date of EUDAMED functionality, in the event of the conclusion, temporary suspension or early termination of a clinical trial, the first, second, third and fifth paragraphs of Article 77 of the Medical Device Regulation shall apply, provided that the Agency's electronic application system is used. (2) As of the date of EUDAMED functionality, Article 77 of the Medical Device Regulation shall apply.

Recording and reporting of adverse events occurring during clinical trials

ARTICLE 14- (1) Until the date of EUDAMED functionality, the first to third paragraphs of Article 79 of the Medical Device Regulation shall apply for the recording and reporting of adverse events occurring during clinical trials, provided that the Agency's electronic application system is used. (2) Until the date of EUDAMED functionality, for post-market studies; instead of the first paragraph, the provisions on vigilance laid down in the relevant legislation for devices placed on the market shall apply. (3) As of the date of EUDAMED functionality, Article 79 of the Medical Device Regulation shall apply.

SECTION FOUR

Responsibilities of the Sponsor and Investigators

Responsibilities of the sponsor and principal investigator with regard to the device for trial purposes

ARTICLE 15- (1) In addition to the provisions set out in the Medical Device Regulation concerning the obligations of the sponsor and investigators with regard to the device for trial purposes; a) It is the sponsor's obligation to ensure that, following the manufacture or import of the device for trial purposes, it is stored in accordance with the characteristics of the product, distributed and delivered to the trial site, installed and maintained, repaired and calibrated where required, that these conditions are maintained at the trial site, that unused products are collected from the trial site for return or disposed of appropriately, and that records of this entire process are kept. b) It is the obligation of the principal investigator at each trial site to take delivery of the device for trial purposes, keep it in safe custody, distribute it in accordance with the written request or the trial protocol, carry out stock control, deal with the remaining portion, and keep records thereof. c) In order for devices not bearing the CE marking to be used for clinical trial purposes, it is mandatory that the information in accordance with Section 23.2 of Section III of Annex I of the Medical Device Regulation be submitted by the manufacturer or authorised representative, as part of the trial applications, via the sponsor to the ethics committee and the Agency. ç) In order for devices for clinical trial purposes not bearing the CE marking to be brought into the country for use in the relevant trials, permission shall be obtained from the Agency by the sponsor. d) The sponsor ensures that the information specified in Article 23 of Section III of Annex I of the Medical Device Regulation accompanies the device. The details on the label shall be indelible, easily legible and clearly comprehensible for the intended user or the volunteers. e) Where the trial is temporarily suspended for safety reasons, all devices for trial purposes remaining at the trial sites shall be immediately withdrawn from the points of distribution by the sponsor, and the situation shall be notified to the Agency, with its documentation and in the form of a report, by the sponsor through the Agency's electronic application system within fifteen days. The withdrawal of the device for trial purposes, the procedures to be carried out and the measures to be taken concerning the withdrawn products shall be specified in detail in the report notified to the Agency.

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Non-substantial changes and notifications

ARTICLE 16- (1) In addition to the provisions set out in the Medical Device Regulation concerning the change and notification obligations of the sponsor and investigators; a) The principal investigator may include in the trial team investigators from other institutions who possess the appropriate qualifications. The application for the appointment of these investigators shall be made in accordance with the procedure specified in paragraph (b). b) During the conduct of the trial, the procedures and principles for non-substantial changes to be submitted to the Agency and the applications thereof shall be determined by the Agency. The Agency evaluates these change applications within thirty working days. c) The progress report of the trial shall be notified to the Agency at least once a year. The ethics committee and the Agency may request a report within a shorter period where they deem necessary or in the case of short-term trials. ç) Change applications and notifications to be made to the Agency specified in this paragraph shall be made by the sponsor through the Agency's electronic application system. (2) The sponsor is responsible for regularly communicating changes and notifications to the ethics committee and the Agency.

Transfer and sharing of duties

ARTICLE 17- (1) Provided that a written contract is concluded, the sponsor may delegate part of its duties to a contract research organisation operating in accordance with scientific principles and good clinical practice. The delegation of duties to the contract research organisation does not relieve the sponsor of any possible legal and criminal liability regarding the delegated matters. The sponsor and the contract research organisation are jointly responsible for the consequences of the contracted works and transactions. (2) References made to the sponsor in this Regulation shall, where applicable, also be deemed to be made to the sponsor's legal representative in accordance with the second paragraph of Article 62 of the Medical Device Regulation or to the contract research organisation to the extent of the delegated duties. (3) The written contracts specified in the first paragraph and the written contract concluded between the sponsor and its legal representative shall be submitted to the ethics committee and the Agency as part of the trial applications. (4) The authority and responsibility for making all applications and notifications to the Agency lie with; a) for sponsors established in Turkey; the sponsor itself or a contract research organisation established in Turkey to which duties have been delegated, b) for sponsors not established in Turkey; the sponsor's legal representative in accordance with the second paragraph of Article 62 of the Medical Device Regulation or a contract research organisation established in Turkey to which duties have been delegated.

Urgent safety measures

ARTICLE 18- (1) In the event that a new situation arises during the conduct of the trial or in connection with the development of the investigational device that may affect the safety of the volunteers, the sponsor or the investigators shall immediately take the necessary urgent safety measures to protect the volunteers against such hazards. The sponsor shall notify the Agency of the information regarding this new situation and the measures taken, via the Agency's electronic application system, within seven days.

Liability

ARTICLE 19- (1) All financial liability of the clinical trial shall be borne by the sponsor and, if any, its legal representative, the contracted research organisations to which tasks have been delegated, and the trial team. (2) No fee whatsoever may be requested from the volunteers for the cost of all investigational products used in the trial, all materials intended for the use of such products, and examinations, audits, analyses and treatments. (3) Trials shall be recorded in a publicly accessible database, provided that the confidentiality of personal data is observed.

SECTION FIVE Miscellaneous and Final Provisions

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Clinical Trials Advisory Board and advisory commissions

ARTICLE 20- (1) The Clinical Trials Advisory Board, established within the Agency and specified in the Regulation on Clinical Trials of Pharmaceuticals and Biological Products, shall, upon the Agency's request, render opinions in all trials subject to the provisions of this Regulation, regarding complaints concerning ethics committees, and matters requiring expert opinion, which are conveyed to the Agency by the ethics committees or by the parties of the trial.

(2) The Agency may seek the opinion of the advisory commissions established within the Agency pursuant to Article 108 of the Medical Device Regulation during the review and assessment of trials and while exercising its powers.

Clinical Trial Ethics Committees

ARTICLE 21- (1) The ethics committees shall assess, monitor and follow up post-market studies and medical device clinical trials in accordance with the provisions of this Regulation, the matters specified in Article 28 of the Regulation on Clinical Trials of Pharmaceuticals and Biological Products, and good clinical practice. (2) The ethics committees shall assess the trials covered by this Regulation within the review periods determined in the Regulation on Clinical Trials of Pharmaceuticals and Biological Products. Where additional information and explanations are required during the review process of the ethics committee, all necessary requests shall be conveyed to the applicant in a single submission. The review process shall be suspended until the requested information and documents are submitted to the ethics committee. (3) In accordance with Article 4 of Section III of Annex XV of the Medical Device Regulation, the assessment of the competence of the monitor to be appointed by the sponsor and of his/her independence from the trial site shall be carried out by the ethics committee assessing the trial. (4) The applications specified in the following Articles of this Regulation must be submitted to the ethics committee before applying to the Agency. The ethics committee decisions regarding these applications shall be submitted to the Agency together with the applications to be made to the Agency: a) The clinical trial application specified in Article 7, b) The substantial modification applications specified in Article 11. (5) The applications and notifications specified below in this Regulation must be submitted to the ethics committee in parallel with the Agency. During its assessment process, the Agency may request the ethics committee decision regarding these applications and notifications: a) The notifications regarding the completion, temporary halt and early termination of the clinical trial specified in Article 13, b) The adverse event notifications specified in Article 14, c) The notification regarding the withdrawal of investigational devices specified in paragraph (e) of the first paragraph of Article 15, ç) The non-substantial modification applications specified in paragraph (b) of the first paragraph of Article 16, d) The progress report notifications specified in paragraph (c) of the first paragraph of Article 16, e) The urgent safety measures specified in the first paragraph of Article 18.

Inspection

ARTICLE 22- (1) The Agency may inspect, with prior notice or without notice, the trials conducted domestically or abroad, the investigators, the locations where the trials are conducted, the sponsors, their legal representatives and contracted research organisations, the sites where investigational devices are manufactured, the laboratories where analyses related to the trial are carried out, the ethics committees and all other parties involved in the trial, with respect to their compliance with this Regulation and other relevant legislation.

Provisions and penalties applicable to non-compliance

ARTICLE 23- (1) The Turkish Penal Code No. 5237 dated 26/9/2004 and other relevant legislation shall be applied to those who act and operate in breach of the provisions specified in this Regulation, according to the nature of their acts.

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Cases not covered

ARTICLE 24- (1) In cases not covered by this Regulation, the provisions of the Medical Device Regulation and of the Regulation on Patient Rights published in the Official Gazette No. 23420 dated 1/8/1998 concerning the rights of the volunteers participating in the trial, as well as other relevant legislation, shall apply.

Repealed Regulation

ARTICLE 25- (1) The Regulation on Clinical Trials of Medical Devices, published in the Official Gazette No. 29111 dated 6/9/2014, has been repealed.

Entry into force

ARTICLE 26- (1) This Regulation shall enter into force on the date of its publication.

Execution

ARTICLE 27- (1) The provisions of this Regulation shall be executed by the President of the Turkish Medicines and Medical Devices Agency (TİTCK).

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