DRAFT REGULATION ON
MEDICAL DEVICE CLINICAL INVESTIGATIONS

CHAPTER 1
Purpose, Scope, Legal Basis and Definitions

Subject

ARTICLE 1 – (1) The purpose of this Regulation is to regulate the procedures and principles regarding post-market clinical follow-up and medical device clinical investigations, and the protection of the rights of subjects who participate in these investigations, within the framework of international agreements, to which being a party, as well as the European Union standards and the good clinical practices.

Scope

ARTICLE 2 – (1) This Regulation shall apply to the post-market clinical follow-up and medical device clinical investigations, as well as the places where investigation can be conducted, and the real or legal persons who will carry out these investigations.

(2) This Regulation does not apply to the performance evaluation studies carried outusing in vitro diagnostic medical devices and to the retrospective studies.

Legal Basis

ARTICLE 3 – (1) This Regulation is prepared based on the the suplemented Article 10 of the Fundamental Law on Healthcare Services published in the Official Gazette dated 7/5/1987 and numbered 3359 and the Articles 508 and 796 of Presidental Decree on the Organization of Affiliated, Related, Associated Institutions and Organizations with Ministries and Other Institutions and Organizations published in the Official Gazette dated 15/07/2018 and No: 4.

Definitions

ARTICLE 4 – (1) The following definitions shall have the meanings designated to them below;

a) Multi-site clinical investigation: A clinical investigation that is conducted in more than one site according to a single protocol and therefore has more than one principle investigator,
b) Audit: the activities of the Agency to examine the sites where clinical investigationconducted, the sponsor, where available, the sites of the legal representative and contract research organization, the documents and records of the investigation, quality assurance regulations and other institutions, boards and organizations, including the ethical committees related to the investigation, in terms of compliance with this Regulation and other relevant legislation.
c) EUDAMED functionality date: The date corresponding to six months after the date of publication by the Commission of a notice in the EU Official Journal according to which EUDAMED, which is the European database on medical devices established by the Commission as spesified in the Article 33 of the Medical Device Regulation published in the Official Gazette dated 2/6/2021 and numbered 31499 (repeated), hasachieved full functionality and meets its functional specifications.
d) Administrative responsible: A physician or a dentist, who completed specialty or PhD training, administratively responsible for the conduct of the investigation in a multi-site clinical investigation,
e) Good clinical practices: The rules to be followed by the parties participating in the investigation, covering the regulations on issues, such as designing, conducting, monitoring, budgeting, evaluating and reporting of the investigation, protecting all the rights and body integrity of the subject, ensuring the reliability of the investigational data, and maintaining the confidentiality, in

order to ensure that the investigations are conducted in accordance with the international scientific and ethical standards,

f) Monitor: The person, being independent of the site of investigation, appointed by the sponsor, to monitor whether the investigation is conducted in compliance with the clinical investigation plan, good clinical practice principles and legislative requirements,

g) Coordinator: The person responsible for the coordination among the investigators of the sites and the ethics committee, the sponsor, where available, the legal representative, and, if necessary, between them and the Agency in a multi-site clinical investigation,

h) Post market clinical follow-up: Studies carried out on subjects to collect the performance or safety data of the device, provided that the device, which is placed on the market by affixing the CE mark on it in conformity with the Medical Device Regulation, is used in accordance with the intended purpose determined by its manufacturer,

i) Retrospective study: Studies in which backdated data were collected,

j) Contract research organization: An independent organization which works in accordance with the principles of good clinical practice, and to which the sponsor has delegated all or some of its duties and authorities related to clinical investigation with a written contract,

k) Medical Device Regulation: Medical Device Regulation published in the Official Gazette dated 2/6/2021 and numbered 31499 (Repeated).

(2) The definitions in the Article 3 of the Medical Device Regulation shall also apply.

CHAPTER 2
General Principles of the Investigation

General principles regarding the clinical investigations

ARTICLE 5 – (1) The provisions of articles 62 to 80 of the Medical Device Regulation, relating to the clinical investigations, shall apply. An act shall be conducted in accordance with the effective dates provided in Article 111 of the Medical Device Regulation in relation to those Articles. The following provisions shall apply in conjunction with the relevant articles of the Medical Device Regulation.

(2) In accordance with the international standards specified in point (a) of the third paragraph of Article 62 of the Medical Device Regulation;

a) It is an obligation that investigational devices had beenfirstly studied in a non-human experimental environment or on a sufficient number of experimental animals.

b) Scientific data, obtained as a result of experiments carried out in a non-human experimental environment or on animals, shall provide sufficient evidence to conduct clinical investigations of the device/devices in terms of achieving the desired aim through the investigation.

c) Any investigation shall not be carried out in a way that disrupts the genetic structure of the subject's germ cells.

(3) Clinical Trials Ethics Committees, whose structure, working procedures and principles are specified in the Regulation on Clinical Trials of Pharmaceuticals and Biological Products published in the Official Gazette dated 13/4/2013 and numbered 28617, and which are approved bythe Agency are authorized for the scientific and ethical examination specified in point (c) of the third paragraph of Article 62 of the Medical Device Regulation. Clinical Trials Ethics Committees are responsible for the examination, monitoring and follow-up of post-market clinical follow-up and medical device clinical investigation, within the framework of their duties and authorities.

(4) Pursuant to point (ı) of the fourth paragraph of Article 62 of the Medical Device Regulation, no convincing incentive or financial offer shall be made to the subject, or his/her legally designated representatives, for the participation of the subjects or the continuation of their participation in the investigation. However, the expenses to be incurred by the participation of the subjects in the

investigation and the deprivation of income arising from the loss of working days of healthy subjects shall be specified in the investigation budget and may be afforded via this budget.

(5) Pursuant to the sixth paragraph of Article 62 of the Medical Device Regulation, investigations shall be conducted by a team of investigators being suitable for the nature of the investigation, led by the principle investigator. A physician or dentist among the investigation team, who has completed his/her specialization or PhD training in the field related to the investigation's topic, is appointed as the principal investigator.

(6) Investigations, pursuant to the seventh paragraph of Article 62 of the Medical Device Regulation, can be conducted in places which are suitable for ensuring the safety of the people on whom the investigation will be carried out, conducting and following up the investigation in a healthy way and, where necessary, making emergency interventions, and which have personnel, equipment and laboratory facilities suitable for the nature of the investigation and, which are preferably designed to conduct a clinical investigation and located in university health practice and research centers, approved research and development centers affiliated to universities and training and research hospitals of the Ministry of Health. When necessary, health institutions and organizations with the specified qualifications may be included in the clinical investigations conducted in these centers and hospitals, provided that they are under the coordination or administrative responsibility thereof. Based on good clinical practices, clinical investigation sites must have at least the following:

a) According to the nature of the investigation, necessary and sufficient personnel and equipment,
b) The place and facilities required for the storage and distribution of the product, depending on the nature of the investigational device,
c) The feasibility and equipment to provide appropriate care for the subject including in situations where prompt remedial action require.
d) Adequate feasibility and equipment, when required, that will allow the subject to be transferred to a more advanced health institution or organization,
d) Adequate feasibility and equipment to keep the information and documents of the clinical investigation and the subjects after the completion of the investigation.

(7) In cases where the subject is not able to give informed consent pursuant to Article 63 of the Medical Device Regulation, the person authorized to give consent for the subject's participation in the investigation pursuant to the legislation in force is considered as the legally designated representative.

(8) The prior interview regarding the informed consent, in accordance with point (c) of the second paragraph of Article 63 of the Medical Device Regulation, is performed by the principal investigator or a physician or dentist who is a part of the investigation team and is authorized by the principal investigator.

(9) In accordance with Article 69 of the Medical Device Regulation, in order to guarantee the subjects against any damage resulting from the participation in a clinical investigation, in all medical device clinical investigations it is obligatory to insure the subjects, however, insurance is not required for medical device clinical investigations in which devices, bearing the CE mark, are investigated in line with the intended use specified by the manufacturer, provided that the ethical committee deems it appropriate according to the benefit-risk ratio. Provided that the final insurance is submitted prior to initiation of the investigation, an insurance offering may be presented in the applications to be submitted to the Ethics Committee and the Agency.

(10) In multi-site investigation, a coordinator is appointed by the sponsor from among the responsible investigators. In both multi-national and multi-site investigations, a coordinator is appointed by the sponsor as the national coordinator among the principle investigators in Türkiye. The investigation site where the coordinator is located is accepted as the coordinating site. The coordinator is required to be

selected from among the principal investigators of the sites that can be the coordinator specified in the sixth paragraph.

Clinical investigations on vulnerable populations

ARTICLE 6 – (1) The provisions of Articles 64 to 68 of the Medical Device Regulation and the following provisions shall apply regarding clinical investigations on vulnerable populations,.

(2) In accordance with the seventh paragraph of Article 63 of the Medical Device Regulation, for the participation of minors in clinical investigations, if the minor is capable of expressing his/her consent, pursuant to Article 63 of the Regulation the written consent of the mother and father or, if under tutorship, the legal represantative, shall be obtained as well as the minor's own consent.

(3) In investigations on incapacitated subjects specified in Article 64 of the Medical Device Regulation; the ethics committee shall be informed about the clinical, ethical, psychological and social problems related to the investigation by a physician who has the expertise in the investigation area and the protocol shall be evaluated accordingly.

(4) In the investigations on minors specified in Article 65 of the Medical Device Regulation; the ethics committee shall be informed about the clinical, ethical, psychological and social problems related to the investigation by a physician who is a specialist in the area of pediatrics, and the protocol shall be evaluated accordingly. Ethics committee shall not approve this investigation without the affirmative opinion of a pediatrician about the investigations on minors.

(5) In investigation on pregnant or breastfeeding women specified in Article 66 of the Medical Device Regulation; the ethics committee shall be informed about the clinical, ethical, psychological, and social problems related to the investigation in terms of pregnant or breastfeedingwomen or embryo, fetus, or newborn child health by a physician who is a specialist in the area of investigation, and the protocol shall be evaluated in this direction.

(6) Additional measures specified in Article 67 of the Medical Device Regulation may also be applied to individuals with limited or reduced autonomy, who are within a certain hierarchical structure or whose ability to protect themselves has not yet developed, decreased or completely disappeared due to economic, social and medical reasons.

(7) In investigations in emergency situations specified in Article 68 of the Medical Device Regulation; the ethics committee shall be informed about the clinical, ethical, psychological and social problems related to the investigation by a physician who is a specialist in the investigation area, and the protocol shall be evaluated in this direction.

(8) In case the matter of the investigation directly concerns the unconscious people or is a situation that can be examined in the unconscious people, or in cases where the existing treatment options for the disease of the unconscious people are completely eliminated, if the investigation does not carry a predictable risk in respect of the health of the unconscious people and if there is a general medical opinion that the investigation will provide a direct benefit to the unconscious people, it may be allowed to conduct investigation on unconscious persons within the framework of the following, together with the issues specified in Article 5 of this Regulation and the fourth paragraph of Article 62 of the Medical Device Regulation:

a) There should be a general medical opinion that the investigation does not pose any known risk to unconscious people.
b) Where applicable, the legal represantative of unconscious peopleshall be informed in accordance with Article 63 of the Medical Device Regulation and their written consent shall be obtained.
c) If unconscious people gain the capacity to come to a conclusion by making an evaluation of the information given to them, in cases they refuse to participate in the investigation or they want to withdraw from the investigation at any stage of the investigation, they will be removed from the investigation immediately.

d) In cases where the written consent of the legal representatives of unconscious people cannot be obtained due to the inability to reach them, unconscious people may be included in the investigation under the responsibility of the principal investigator or a investigator who is a physician, provided that the following conditions are met in addition to the provisions of the first paragraph:
   1) The ethics committee has previously evaluated whether the proposed investigation protocol or other documents adequately meet the ethical issues for the investigation,
   2) There is a general medical opinion that the investigation will provide a direct benefit to the unconscious people, in cases where the physician should intervene immediately, such as cardiac arrest, head trauma, central nervous system infections, intracranial hemorrhage, and in cases the existing treatment options are completely eliminated.

CHAPTER 3
Initiation and Conduct of investigations

Application for clinical investigations

ARTICLE 7 – (1) The following provisions apply to applications for clinical investigations until EUDAMED functionality date:

a) The sponsor of the clinical investigation shall submit an application by means of the electronic application system of the Agency accompanied by the documentation referred to in Chapter II of Annex XV to the Medical Device Regulation.
b) In case the application is duly submitted, and there is no incompleteness in the information and documentation needed to be submitted in the application, it is essential that the application is assessed by the Agencyand concluded within twenty working days.
c) Clinical investigations shall not be initiated without the permission of the Agency.

(2) From the date of functionality of EUDAMED, Article 70 of the Medical Device Regulation shall apply.

Assessment of application for a clinical investigation

ARTICLE 8- (1) The Agency shall assess applications for clinical investigations in line with the issues stated in Article 71 of the Medical Device Regulation. The reference made to the completeness of the application in point (a) of the fourth paragraph of the relevant article shall also be deemed to have been made to points (a) and (b) of the first paragraph of Article 7 of this Regulation.

(2) In multi-site clinical investigations, it is sufficient to have a single ethical committee decision. In the applications to be submitted to the Agency, the decision of the ethics committee is presented as a part of the application.

(3) While submitting to the Agency, previous negative ethics committee decisions shall be submitted to the Agency at the time of application, even if the relevant investigation has been approved by the same ethics committee.

Conduct of a clinical investigation

ARTICLE 9- (1) The provisions of Article 72 of the Medical Device Regulation regarding the conduct of a clinical investigation shall apply.

(2) In order to keep the identities of the subjects involved in the investigation confidential, when reporting any adverse event or investigation-related data by the principal investigator or other investigators, instead of the subject's name and identifying information, the subject code given to each subject shall be used.

(3) No personal data of the subjects shall be publicly available in any way.

Post-market clinical follow-up

ARTICLE 10- (1) For post-market studies until the EUDAMED functionality date, the following provisions shall apply:

a) Articles 62 to 69 of the Medical Device Regulation and the third to tenth paragraphs of Article 5 of this Regulation,

b) Article 6, first paragraph of Article 7, Articles 8 and 9, first paragraph of Article 11, first paragraph of Article 12, first paragraph of Article 13 and first and second paragraphs of Article 14 of this Regulation,

(2) From the date of functionality of EUDAMED, Article 74 of the Medical Device Regulation shall apply.

Substantial modifications to clinical investigations

ARTICLE 11 – (1) Until EUDAMED functionality date, for the modifications (substantial modifications) to a clinical investigation that are likely to have a substantial impact on the safety, health or rights of subjects, or the robustness or reliability of clinical data generated by the investigation;

a) The sponsor of the clinical investigation shall notify by means of electronic application system of the Agency, of the nature of and reasons for those modifications preferred to introduce. Current versions of the documentation referred to in Chapter 2 of Annex XV to the Medical Device Regulations shall be provided as part of this application. modifications to relevant documents should be clearly discernible.

b) In case the application is duly submitted, and there is no incompleteness in the information and documentation needed to be submitted in the application, it is essential that the application is assessed by the Agency and concluded within twenty working days.

c) The Agency shall assess the applications for substantial modifications in line with the issues stated in Article 8 of this Regulation.

d) Substantial modifications shall not be implemented without the permission of the Agency.

(2) From the date of functionality of EUDAMED, Article 75 of the Medical Device Regulation shall apply.

Corrective measures

ARTICLE 12 –(1) For the corrective measures to be taken in investigations until the EUDAMED functionality date, the first and second paragraphs of Article 76 of the Medical Device Regulation shall apply.

(2) From the date of functionality of EUDAMED, Article 76 of the Medical Device Regulation shall apply.

Information from the sponsor at the end of a clinical investigation or in the event of a temporary halt or early termination

ARTICLE 13 – (1) In the event of termination, temporarily halting and early termination of a clinical investigation until the EUDAMED functionality date, provided that the electronic application system of the Agency is used, the first, second, third and fifth paragraphs of Article 77 of the Medical Device Regulation shall apply.

(2) From the date of functionality of EUDAMED, Article 77 of the Medical Device Regulation shall apply.

Recording and reporting of adverse events that occur during clinical investigations

ARTICLE 14 – (1) For recording and reporting of adverse events that occur during clinical investigations until the date of EUDAMED functionality; provided that the electronic application system of the Agency is used, paragraphs one to three of Article 79 of the Medical Device Regulation shall apply.
(2) For post-market clinical follow-up until the EUDAMED functionality date; instead of the first paragraph, the provisions regarding vigilance stated in the relevant legislation shall apply for the devices placed on the market.
(3) From the date of functionality of EUDAMED, Article 79 of the Medical Device Regulation shall apply.

CHAPTER 4
Responsibilities of the Sponsor and Investigators

Responsibilities of the sponsor and principal investigator regarding the investigational device
ARTICLE 15 – (1) In addition to the provisions specified in the Medical Device Regulation regarding the obligations of the sponsor and investigators regarding the investigational device;

a) After the manufacturing or importing of the investigational device; storage, distribution, and delivery to the site of investigation in conformity with the product characteristics, if necessary, the installation and maintenance, repair, calibration procedures, as well as the maintenance of these conditions in the site of investigation, the collection of unused products from the site of investigation and their return or properly destruction, and keeping the records of this whole process are responsibilities of the sponsor.
b) Receiving of the investigational device, its storage, distribution in compliance with the written request, or distribution, stock control, operations to be made to the surplus and keeping the records in conformity with investigation protocol are under the responsibility of the principal investigator in each site where the investigation is conducted.
c) In order for devices that not currently bear the CE marking to be used for clinical investigation purposes, it is obligatory that the information compliant with section 23.2 of Chapter 3 of Annex I to the Medical Device Regulation is provided to the Ethics Committee and the Agency through the sponsor as part of the applications for investigation by the manufacturer or the authorized representative.
d) Permission shall be obtained from the Agency by the sponsor in order to bring the investigational devices, that not currently bear the CE marking, to the country for use in the relevant investigations.
e) Sponsor shall ensure that the device is accompanied by the information specified in section 23 of Chapter 3 of Annex I of Medical Device Regulation. Details on the label; shall be indelible, easily readable and clearly understandable to the intended user or the subject.
f) In the event that the investigation is temporarily halted on safety grounds, the sponsor shall immediately withdraw all investigational devices present in the site of investigation from the distribution locations, and inform the Agency by means of the electronic application system of the the Agency thereof together with the documentation and in a report within 15 days. The withdrawal of the investigational device and the procedures to be made and the measures to be taken regarding thereof shall be specified in detail in the report submitted to the Agency.

Nonsubstantial modifications and notifications
ARTICLE 16 – (1) In addition to the provisions stated in the Medical Device Regulation regarding the modification and notification obligations of the sponsor and investigators;

a) The principal investigator may include investigators with appropriate qualifications from other institutions within the investigation team. The application for the assignment of those investigators shall be made through the procedure specified in point (b).
b) During the conduct of the investigation, the procedures and principles regarding the nonsubstantial modifications that should be submitted to the Agency and applications thereof shall be established by the Agency. The Agency shall evaluate those applications for modifications within thirty working days.
c) The progress report of the investigation shall be notified to the Agency at least once a year. The Ethics Committee and the Agency may request a report in a shorter time, where deemed necessary or in short-term studies.
d) Applications for modifications and notifications to be made to the Agency specified in this paragraph shall be made by the sponsor by means of electronic application system of the Agency.

(2) The sponsor shall be responsible for regularly transmission of modifications and notifications to the Ethics Committee and the Agency.

Duty delegation and sharing

ARTICLE 17 – (1) Provided that a written contract is made, the sponsor may delegate some of its duties to a contract research organization which operates in accordance with scientific principles and good clinical practices. Delegation of duties to the contract research organization shall not prejudice to possible legal and criminal liability of the sponsor for the delegated issues. The sponsor and the contract research organization are jointly liable for the results of the contracted works and transactions.

(2) References made to the sponsor in this Regulation are also considered to be made to the legal representative of the sponsor or to the contract research organizations within the scope of their duties, pursuant to the second paragraph of Article 62 of the Medical Device Regulation, where applicable.

(3) The written agreements specified in the first paragraph and the written agreement between the sponsor and its legal representative shall be submitted to the ethics committee and the Agency as part of the applications for investigation.

(4) The followings are authorized and responsible for all applications and notifications to be made to the Agency:

a) For sponsors established within Türkiye; the sponsor itself or contract research organization that is established within Türkiye and whose duty delegation has been made,
b) For sponsors not established within Türkiye; pursuant to the second paragraph of Article 62 of the Medical Device Regulation, the legal representative of the sponsor or contract research organization that is established within Türkiye and whose duty delegation has been made,

Emergency safety measures

ARTICLE 18 – (1) In the event of a new situation that may affect the safety of the subject during the conduct of the investigation or regarding the development of the investigational device, the sponsor or investigators shall immediately take the necessary emergency safety measures to protect the subjects against those dangers. The sponsor shall notify the Agency about this new situation and the measures taken, in terms of the electronic application system of the Agency, within seven days.

Responsibility

ARTICLE 19 – (1) All financial responsibility of the clinical investigation belong to the sponsor and, if applicable, its legal representative, delegated contract research organizations and the research team.

(2) No fee shall be charged to the subject for any investigational product used in the investigation, any materials specific to the use of those products and the cost of examination, analysis, assay and treatments.
(3) Investigational data shall be recorded in a public database, provided that the confidentiality of personal data is respected.

CHAPTER 5
Final Provisions

Clinical Trials Advisory Board and Advisory Commissions
ARTICLE 20 – (1) The Clinical Trials Advisory Board, which is specified in the Regulation on Clinical Trials of Pharmaceuticals and Biological Products and is established within the Agency, shall issue an opinion, in case of request by the Agency, on the complaints regarding the ethics committees in all investigations governed by the provisions of this Regulation and on matters that are submitted to the Agency by the ethics committees or the parties of the investigation and require expert opinion.
(2) The Agency may seek the opinion from the advisory commissions, established within the Agency pursuant to Article 108 of the Medical Device Regulation, during the examination and evaluation of the investigation and while exercising its authority.

Clinical Trial Ethics Committees
ARTICLE 21 – (1) Ethics committees shall evaluate, monitor and follow-up post-market clinical follow-up and medical device clinical investigations in line with the provisions of this Regulation as well as the issues specified in Article 28 of the Regulation on Clinical Trials of Pharmaceuticals and Biological Products and good clinical practices.
(2) Ethical committees shall evaluate the investigations covered by this Regulation within the review periods specified in the Regulation on Clinical Trials of Pharmaceuticals and Biological Products. In case of additional information and explanations are needed during the review process of the ethics committee, all necessary requests shall be forwarded to the applicant at once. The review process shall be suspended until the requested information and documents have been submitted to the ethics committee.
(3) In accordance with Section 4 of Chapter 3 of Annex XV to the Medical Device Regulation, the examination of the competence of the monitor to be appointed by the sponsor and independence thereof from the site of investigation shall be made by the ethics committee evaluating the investigation.
(4) The following applications specified in this Regulation shall be submitted to the ethics committee before making application to the Agency. Ethics committee decisions regarding these applications shall be provided to the Agency together with the applications to be made to the Agency:
a) The application for clinical investigation specified in Article 7,
b) Applications for substantial modifications specified in Article 11.
(5) The following applications and notifications specified in this Regulation shall be submitted to the Agency and the ethics committee, concurrently. The Agency may request an ethics committee decision regarding these applications and notifications during the evaluation process:
a) Notifications regarding the termination, temporary halt and early termination of the clinical investigation specified in Article 13,
b) Adverse event notifications specified in Article 14,
c) Notification regarding the withdrawal of investigational devices specified in point (e) of the first paragraph of Article 15,
d) Applications for nonsubstantial modifications specified in point (b) of the first paragraph of Article 16,
d) Notifications of progress report specified in point (c) of the first paragraph of Article 16,

e) Emergency safety measures specified in the first paragraph of Article 18.

Inspection
ARTICLE 22 – (1) Agency may audit the investigations carried out in the country or abroad, investigators, sites where investigations are conducted, sponsors, legal representatives and contract research organizations, places where investigational devices are manufactured, laboratories where analyzes regarding investigation are made, ethical committees and all other parties within the scope of investigation in terms of compliance with the provisions of this Regulation and other relevant legislation, with or without prior announcement.

Provisions to be applied on improper actions and penalties
ARTICLE 23 – (1) The provisions of the Turkish Penal Code dated 26/9/2004 and numbered 5237 and other relevant legislation shall be applied to those, who act and operate in violation of the provisions specified in this Regulation, according to the nature of the actions.

Cases where there is no provision
ARTICLE 24 – (1) In this Regulation, in cases where there is no provision, the provisions specified in the Medical Device Regulation and, as regards the rights of the subjects who participate in the investigation, the Patient Rights Regulation published in the Official Gazette dated 1/8/1998 and numbered 23420, and the provisions of other relevant legislation shall apply.

Repealed regulation
ARTICLE 25 – (1) The Medical Device Clinical Investigation Regulation published in the Official Gazette dated 6/9/2014 and numbered 29111 has been repealed.

Entry into force and date of application
ARTICLE 26 – (1) This Regulation shall enter into force on the day of publication.

Enforcement
ARTICLE 27 – (1) The provisions of this Regulation are executed by the President of the Turkish Medicines and Medical Devices Agency.