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1. SCOPE AND FIELD OF APPLICATION

This regulation **(MDR.GD.001)** defines the rights, responsibilities, and operational methodology governing the relationship between Kiwa Belgelendirme Hizmetleri A.Ş.(hereinafter referred to as Kiwa TR) and the Organization[1] in the implementation of procedures for assessing the conformity of medical devices[2] (hereinafter referred to as MD) provided for in EU Regulation 2017/745 (as referred to in Annexes IX and XI of the Regulation).

In addition, conformity assessment activities are carried out in accordance with the harmonised standards, the Common Specifications and to the European guidelines applicable to the medical sector, in force at the time of the execution of the activities.

The requirements set out in this regulation **(MDR.GD.001)** form an integral part of the contract envisaged with Kiwa TR. (economic offer, Kiwa Certification Regulation, and Kiwa TR's General Terms and Conditions for the fulfillment of orders (hereinafter referred to as the General Terms and Conditions)).

These requirements refer solely to aspects specifically connected with the scope of the requested certification.

The types of MDs for which Kiwa TR is authorised to operate, are set out in the notification issued to Kiwa TR by the Competent Authority, available on the https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies/notifications/1007731?organizationVersion=18 .

The contract expressly excludes any form of consultancy to the Organisation that could jeopardise the nature of independence of the carried-out assessments.

2. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER

Kiwa TR applies the following principles and commitments in its certification activity and the *General* Terms and Conditions:

a) **Non-discrimination:** In accordance with this Regulation, access to certification services shall be provided to all organizations requesting them, without discrimination on commercial or financial grounds or on grounds of membership of particular associations.

b) **Impartiality and independence:** ensured through the following measures:

- On time implementation of formalised rules and procedures in use by all personnel involved in certification and periodic consultation with appropriate parties interested in certification.
- Certification activities are carried out by personnel who have no conflict of interest with the Organization to be serviced and who are required to comply with the rules of conduct and independence principles established by Kiwa TR.
- For this reason, Kiwa TR undertakes to accept any reasoned report from the Organization within **3 working days** of the names being notified to the Organization regarding the existence of any conflict of interest that could jeopardize the impartiality or independence of the assessment.
- A clear distinction is made between personnel conducting audits and personnel responsible for certification decisions.
- Kiwa TR completely refrains from providing consulting services for the identification and implementation of requirements for certification.

c) Prompt management of complaints, appeals and disputes, as defined in article 8 of this regulation;

d) **Confidentiality:** in addition to that provided for in *the General Terms and Conditions* and *The Kiwa Regulation for Certification*, all data and information of Customers are treated with the utmost confidentiality, subject to that provided for otherwise by law.

[1]The term “Organization” means any “economic operator”, as defined in art. 2 point 35 of Regulation (EU) 2017/745, to which this Regulation applies. For Kiwa TR, the terms Organisation and Customer are synonyms.
[2]For the definition of medical device, and other specific definitions of the sector, provided for in Article 2 of EU Regulation 2017/745 apply.

Kiwa TR requires all its personnel, including those performing conformity assessments, to sign a document that includes a confidentiality agreement and a commitment to appropriately handle all information they may have access to.

A similar commitment concerning the confidentiality is guaranteed by Control Bodies and Competent and Designating Authorities, to which Kiwa TR must guarantee access to Customer data.

Information exchanged confidentially between competent authorities and the former as well as the European Commission is not disclosed unless such is agreed with the authorities that transmitted them.

The confidentiality requirements do not prejudice the rights and duties of the Commission, Member States, and notified bodies concerning information exchange and the disclosure of safety notices, as well as the duties of persons required to provide information in accordance with criminal law.

The European Commission and Member States can exchange confidential information with the regulatory Authorities of non-EU countries with which they have concluded bilateral or multilateral confidentiality agreements.

e) **Designation as Notified Body:** Kiwa TR undertakes to inform the Organisation of any rejection, restriction, suspension, or withdrawal of the accreditation and/or ministerial notification; in such cases, Kiwa TR will be in no way responsible for any damages caused to the Organisation by rejection, restriction, suspension, or withdrawal of the notification; in the aforementioned cases, the Organisation has the right to opt out of the contractual relationship with Kiwa TR without the need for prior notification and without any additional costs.

If the designation has been suspended, restricted or withdrawn in whole or in part, Kiwa TR will follow the direction provided by the responsible authority and inform the Customers concerned **at the latest within ten days** of the decision.

If Kiwa TR decides to terminate conformity assessment activities, it will inform the responsible authority of the notified bodies and the manufacturers concerned as soon as possible and, if the termination has been scheduled, **a year before** the termination of activities.

The certificate issued to the Organisation can remain valid (at the sole discretion of Kiwa TR) for a temporary period of six months after Kiwa TR ceases to carry out its activities, provided that another notified body has confirmed in writing that it will assume responsibility for the devices covered by the certificate in question.

f) Kiwa TR undertakes to provide, upon request, a list of any subsidiaries used as part of the certification activities covered by this Regulation.

g) For outsourced activities, Kiwa TR agrees to inform the Organisation as regards subcontractors used.

Kiwa TR does not subcontract the following activities:

2017/745 EU Annex-VII Article 4.3. Application review and contract, 4.4. Allocation of resources, 4.7. Final review, 4.8. Decisions and Certifications; with these, especially :

— review of the qualifications and monitoring of the performance of external experts

— auditing and certification activities where the subcontracting in question is to auditing or certification organisations

— allocation of work to external experts for specific conformity assessment activities

— final review and decision making functions

h) Kiwa TR makes all contracts related to conformity assessment activities directly with the manufacturer, not with other organisations.

i) In cases where the audit and assessment service provided is required to be performed again due to Kiwa TR; No additional fee is charged to the customer for the audit and assessment repetition.

j) Kiwa TR undertakes that, if it uses a subcontractor for any conformity assessment activity, the subcontractor fully complies with the requirements of EU Regulation 2017/745.

k) If Kiwa TR assigns any conformity assessment activity to a subcontractor and / or external expert; this subcontractor and / or external expert cannot transfer the assignment to another organization or personnel.

3. REQUIREMENTS FOR THE CERTIFICATION

3.1 General Obligations of the Organization

In addition to the provisions of the General Terms and Conditions **(SD.011)** and the Kiwa Certification Regulation **(MDR.GD.001),** the Organization (or its representative) must undertake to comply with the following obligations during the application for certification:

- Accept the conditions set out in this Regulation **(MDR.GD.001)** which is also available on the Kiwa TR website (https://www.kiwa.com/tr/tr).

  In any case the Organizations that intend to conclude a contract with Kiwa TR can request a computer copy.

  Kiwa TR will communicate all subsequent and possible modifications to the contractual documents, but it is the responsibility of the Organization to always have the updated version of these documents, downloading them from the website https://www.kiwa.com/tr/tr

- All requirements under EU Regulation 2017/745 (including Article 10) shall apply (for all entities involved in the life cycle of the certified MD) and appropriate contracts shall be made with the relevant parties (manufacturer, importer, exporter, distributor).
- Maintaining MD compliance with the essential requirements referred to in Annex I of 2017/745 EU Regulation.
- Provide Kiwa TR with all necessary information concerning the Organisation, the products or categories of products subject to the certification procedure and any critical[3] suppliers entrusted with outsourced processes, including all information concerning obligations related to the UDI system referred to in Articles 27, 29 and 31 of Regulation 2017/745.
- Inform Kiwa TR of all the places in which the device is designed and manufactured, particularly if said places do not correspond to the Organisation's (or its Authorised Representative's) operational headquarters.
- During the offer acceptance phase, expressly declare not to have submitted the application for certification, for the certification related to the device, to another Notified Body; or provide information on any previous application requests, for certification relating to the device, which have been rejected or have been withdrawn.
- Authorise personnel appointed by Kiwa TR the access to premises as necessary to perform conformity assessment activities, including those for documentary analysis, and access during the audit to all the areas subject to assessment, to documents and recordings (including reports of internal audits) as well as personnel involved in handling complaints.

  Appoint its own Representative as the main contact person of the conformity assessment team and guarantee that any consultant present during the audit solely remains an observer.
- Be responsible for applying the requirements prescribed by laws in force on safety in the workplace.

  The organisation undertakes to provide Kiwa TR with a complete and detailed report of the specific risks that exist in the workplace where Kiwa TR personnel will be working and PPE necessary for carrying out the appointment, informing Kiwa TR personnel concerning their correct use.

  In this regard, the organization has to provide appointed Kiwa TR personnel with the company documentation concerning workplace safety (risk assessment document, safety plan, procedures, etc.), limited to aspects of specific interest.

  If for such omissions, injuries occur or illnesses are contracted, no charges may be made, for any reason against Kiwa TR.
- Provide Kiwa TR with all technical documentation and quality system documentation, both during the initial phase as well as in any other phase of the certification process.

[3] Critical suppliers: supplier (or subcontractor) of critical components (critical raw materials, primary packaging, critical semi-finished products, etc.), of complete devices, or of essential processes for ensuring compliance with the provisions of the law (design, special or customised components, special processes, software, tests and controls, etc.).

- Provide all the documentation subject to assessment by Kiwa TR and the relative correspondence with Kiwa TR, in Turkish or(/and) English.

  No other languages shall be accepted.

- Documentation must be dated and signed, in uneditable format.

  Any changes to the contents of the documents being assessed must be identified, in order to guarantee immediate traceability with respect to the previous revision.

  This process for managing changes must be formalised within the organisation's quality management system.

- All documents submitted by the Applicant Customer Organisation within the scope of the audit must be authentic, valid and original. The Customer Organisation guarantees the authenticity, validity and originality of all documents within the scope of the audit. Within the framework of this guarantee, the Certification Body shall have no obligation to conduct any additional research or verification regarding the documents. If, for any reason, it is determined that the documents submitted by the Customer Organisation within the scope of the conformity assessment have been altered, are forged, invalid, etc., the certificates issued to the Customer Organisation as a result of the audit may be cancelled, suspended or withdrawn. In this case, the Customer Organisation shall be liable for all damages incurred by the Certification Body.
- Ensure the registration/information procedures provided for by the Competent Authority.
- Fulfill the obligations imposed by the quality system approved by Kiwa TR and ensure its proper and effective functioning for the entire life cycle of the MD subject to certification.

  These obligations also include the systematic updating of documentation in line with legislative updates, guidelines, and the state of the art of the relevant sector.

- Inform the competent authorities and Kiwa TR without delay and as soon as it becomes aware of any incidents or possible serious risks associated with the MD made available in the territories of the European Union, as provided for by Articles 87 and 88 of EU Regulation 2017/745; moreover, in the event of a serious incident, it must carry out all activities laid down in Article 89 of EU Regulation 2017/745.
- For all critical suppliers, a contractual arrangement must be made with Kiwa TR to grant access to all supplier sites where certified medical devices are manufactured or processed, as well as to the relevant documentation (including lower levels of the supply chain where applicable). This access must cover both periodic and unannounced audits. If this access cannot be provided, Kiwa TR may reject the certification request or terminate the current certification process.

  The supplier must also provide the Organisation with all of the technical documentation and quality management system documentation required to provide proof of compliance with the relevant safety and performance requirements and application of the quality management system.

- It must keep an up-to-date list of codes corresponding to all approved and signed devices subject to certification and ensure that they are transmitted to Kiwa TR in a controlled manner.
- For all extensions to new products subject to certification, the above obligations must be maintained in the event of changes to certified products.
- The possible presence of control body/competent authority personnel as observers is accepted without additional cost, with Kiwa TR clearly stating their roles and informing them.

  The purpose of these observers is to assess whether the assessment methods used by Kiwa TR comply with the notification requirements.

Specific obligations of the Organisation in relation to the conformity assessment Annexes

The Organisation must undertake to comply with the following requirements:

- To subject an MD to conformity assessments in accordance with the selected Annex before placing it on the market and putting it into service.
- Plan, continuously implement and document clinical evaluation and post-market clinical follow-up (PMCF) as specified in Annex XIV of EU Regulation 2017/745 and in the relevant guidelines and common specifications published by the European Commission.

- Where applicable, carry out clinical investigations according to Annex XV of EU Regulation 2017/745 and the related guidelines and Common Specifications published by the European Commission.
- **For all MDs:** prepare technical documentation according to the chosen Annex.
- **For class IIa, IIb and III MDs:** draft and maintain a periodic safety update report (PSUR) as provided for in Article 86 of EU Regulation 2017/745.
- **For class Is, Im and Ir MD's:** draft and maintain a post-marketing surveillance report (PMSR) as provided for in Article 85 of EU Regulation 2017/745.
- **For implantable and class III MD's:** draw up a summary of safety and clinical performance as article 32 of EU Regulation 2017/745.

  The manufacturer shall draw up the SSCP based on the clinical evaluation and the post-market surveillance of the device. The SSCP shall include information on the identification, intended purpose, description, alternatives, standards, clinical evaluation, user profile, and residual risks of the device.

  The manufacturer shall submit the draft of the SSCP to Kiwa TR. Kiwa TR validates the SSCP and uploads it to EUDAMED. The manufacturer shall mention on the label or instructions for use where the SSCP is available.

  Kiwa TR monitors the SSCP as part of the surveillance activities and ensures that it is updated in accordance with the changes in the device or the clinical data. Kiwa TR also verifies that the SSCP is consistent with the technical documentation and the certificate of the device.
- Maintain, in the technical documentation, an updated list of all the UDI-DIs attributed to the MD subject to certification.
- A procedure is established and implemented to manage changes that impact products subject to certification or the approved quality system. This procedure ensures that information regarding the changes is sent to Kiwa TR and that approval is obtained from Kiwa TR before any modifications are implemented (ref. Article 4.6.1).
- The Competent Authorities and Kiwa TR agree to make available the following for a period of at least ten (10) years and for implantable devices for at least fifteen (15) years from the date of entry of the last device on the market.

  a) Prepares an EU declaration of conformity in accordance with the provisions of Annex IV of EU Regulation 2017/745.

  b) Provides the documentation specified in the fifth paragraph of section 2.1 of Annex IX to EU Regulation 2017/745.

  c) Provides information on the changes referred to in paragraph 2.4 of Annex IX to EU Regulation No. 2017/745.

  d) Saves Kiwa TR's decisions and reports provided in accordance with Annex IX of EU Regulation 2017/745.

  In addition, for Annex IX only:

  e) The EU certificate of technical documentation and the EU certificate of quality management system.

  f) The data and records resulting from the procedures referred to in point 2.2, second paragraph, letter (c), of Annex IX of EU Regulation 2017/745.

  g) The documentation referred to in paragraph 4.2 of Annex IX of EU Regulation 2017/745.

  ***In addition, for Annex XI only*:** The EU type examination certificate referred to in Annex X (if applicable) and the EU quality assurance certificate.

3.2 Description and Classification of results of conformity assessment activities

The results of the documentary analysis are expressed in terms of *findings*.

Findings: non-fulfilment of requirements in the technical documentation and quality management system applied to the MD subject to certification. In addition, a finding may also be issued in relation to other documentation not specifically required, but whose deficiency may affect the compliance of the MD.

The results of the audit are classified as follows:

Major non-conformity (NC): non-fullfillment of a requirement established by applicable regulations or by the Organisation's documentation approved by Kiwa TR, which affects the capacity of the product to achieve the

expected results, and therefore the safety, fundamental performance, technical specifications or functionality of the product. It may concern:

- Deviation or total lack of compliance with respect to a specified requirement, identified on the basis of objective evidence;
- non-conformity with applicable legal requirements.

Minor non-conformity (NC): non-fullfillment or partial fulfillment of a requirement specified in the applicable regulations or in the documents approved by Kiwa TR, which does not affect the product's ability to achieve the expected results despite requiring correction and therefore does not constitute a major nonconformity as described above.

Several minor non-conformities pertaining to the same requirement, depending on the content and the general outcome of the Audit, can lead to a major NC being issued.

Minor non-compliances that have not been resolved and/or not managed by the Organisation may determine the issuance of a Major NC.

Opportunity for improvement: that not covered in the definitions of a NC, which consists of a potential improvement of the management system or product subject to certification.

4. REQUIREMENTS OF THE CONFORMITY ASSESSMENT PROCESS

4.1 General requirements

*4.1.1. Assumption of Conformity

The activities of Kiwa TR are carried out in accordance with all of the requirements that must be held by Notified Bodies, as prescribed at a national level by the Competent Authority.

Medical devices compliant with the relevant harmonized standards (including monographs of the European Pharmacopoeia and the Common Specification) or to relevant parts of these standards, whose references are published in the Official Journal of the European Union, are considered compliant with the provisions of EU Regulation 2017/745.

This requirement also applies to quality management systems, to risk management, to post-marketing surveillance systems, to clinical investigations, to clinical evaluations or to *post-marketing clinical follow-ups* (PMCF).

Kiwa TR shall operate in compliance with Regulation (EU) 2017/745 and with all the guidance documents indicated above and applicable to the medical device sector.

4.1.2 Classification of the MD

The Organisation who intends to work with Kiwa TR for CE marking of its MD is responsible for the specific intended use assigned to each device and its classification as reported in Article 51 and in Annex VIII of EU Regulation 2017/745.

Kiwa TR, during the review of the certification application, shall verify the classification assigned by the Organisation for approval.

In case of a disagreement between the Organisation and Kiwa TR regarding the application of the classification rules, Kiwa TR shall inform the Organisation on the matter.

The Organization is responsible for submitting details of any dispute to the Competent Authority with the power to make decisions on the matter. Upon request, Kiwa TR may make this submission on behalf of the Organization.

Where the Organisation does not have its registered office within the European Union, the matter shall be submitted to the competent Authority of the Member State in which the authorised representative is established.

If the Organisation is located in a Member State other than Turkey, the Competent Authority of the Organisation’s Member State shall make a decision on the matter, after consulting the Turkish Competent Authority.

When evaluating the classification of the medical device; the following external documents are also taken into consideration.

- **MDCG 2021-24 Guidance on classification of medical devices:** This document provides a general overview of the purpose and practical relevance of medical device classification, as well as detailed explanations of the 22 classification rules under the MDR.

- **MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746–IVDR**: This guide is primarily aimed at Medical Device Software (MDSW) manufacturers, provides guidance on the eligibility criteria for software falling under the scope of Medical Device Regulations, including Medical Device Artificial Intelligence (MDAI), the application of classification criteria under such regulations to MDSW, and information related to the market release of MDSW. The criteria specified in this document also applies to applications (commonly referred to as 'apps'), regardless of their location i.e. may they be operating on a mobile phone, on the cloud or on other platforms.
- **MDCG 2023-5 Guidance on qualification and classification of Annex XVI products:** This guidance document provides elements useful for the qualification of a product as a product without an intended medical purpose listed in Annex XVI to the MDR. It also provides explanations and examples for the application of certain classification rules to products without an intended medical purpose, hereinafter also referred to as devices. The examples provided do not imply that the products are a priori qualified as devices. Classification rules apply after the qualification of the product as a device has been established.This guidance document should be used in conjunction with the MDCG 2021-24 on classification of medical devices and take into consideration Commission Implementing Regulation (EU) 2022/2347 on reclassification.
- **Helsinki Procedure** for borderline and classification under MDR & IVDR
- **(EU) 2022/2346** Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (Text with EEA relevance) (including regulation no. 2023/1194)
- **Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices:** This manual contains examples of borderline and classification cases for medical devices and in vitro diagnostic medical devices, based on the opinions of the Medical Device Expert Group
- **MDCG 2022-5 Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices:** This document provides guidance on how to distinguish between medical devices and medicinal products, taking into account the definitions, criteria and principles laid down in the relevant EU legislation.

4.1.3 Certification process

The certification path followed by Kiwa TR for the purposes of CE marking and the maintenance thereof is represented by the provisions set out in Annex IX or in Annex XI of EU Regulation 2017/745, to which reference should be made.

Kiwa TR, during the review of the certification application, shall verify the conformity assessment process defined by the Organisation for approval.

Kiwa TR performs conformity assessments for the device groups listed in Annex XVI in accordance with the guidelines for comparable medical devices and in light of the Common Specifications applicable to each group in terms of clinical evaluation and risk management.

For Class I devices with a measuring function, sterile Class I medical devices, or reusable Class I surgical instruments, Kiwa TR limits its involvement in the conformity assessment process to the verification, implementation, and maintenance of sterility, metrological requirements, and reusability, as stipulated in Article 52(7) of EU Regulation 2017/745.

For all devices to which other regulations or directives apply (e.g. Directive 2006/42/EC, Directive 89/686/EEC), the Organisation must also refer to the requirements set out in these documents.

The activities described below should be performed after each audit:

- After each audit, the conformity assessment Team meets for the assessment of the recorded evidence, their classification and the drafting of a report.
- In the final meeting, the conformity assessment Team submits the Audit results and the conclusions on compliance with the Management System applied, mentioning any non-conformity found. At the end of the meeting, Lead Auditor issues a Report that outlines the results of the Audit.

- Any diverging opinions between the conformity assessment Team and the Organisation regarding audit findings or conclusions must be discussed and resolved, where possible. In the event of any non-resolved differences of opinion, the Organization can express its reservations on the results of the Audit.
- In the event that NCs are recorded, the Organisation must define and implement appropriate measures, a root cause analysis and corrective actions, with a precise, clearly planned process with respect to the methods and timing of implementation.

  The Organisation must notify said action plan to Kiwa TR within a certain period, as provided in the following paragraphs.
- The opportunity for improvement must be analysed by the Organisation, who will decide whether to define the subsequent actions for their implementation or not.

  If the Organisation decides not to act on the Opportunity for Improvement, it must report the analysis performed and the reasons for non-transposition; in the latter case, Kiwa TR reserves the right to further examine the aspect reported.
- All conformity assessments and tests carried out during the certification process shall be made available to the Competent Authorities and other interested parties, as provided for by Annex XII of Regulation 2017/745, informing the Organisation.

4.1.4 Specific additional procedures

For some types of MD's, Regulation 2017/745 provides for consultations with the Competent Authorities or an expert panel referred to in Article 106, in specific phases of the process described below.

Depending on the opinion expressed, Kiwa TR shall evaluate the consequent actions to be taken including specific limitations or conditions (see Article 4.9).

The scientific opinion resulting from the consultations carried out must be part of the technical documentation pertaining to the MD.

a) For implantable class III devices and rule 12 class IIb active devices intended to administer a medicinal product to the body and/or to remove it from the body (pursuant to Regulation 2017/745 Article 54), except in cases deemed not applicable, Kiwa TR shall carry out the evaluation of the clinical data made available by the organization, but it shall not be able to proceed with the conclusion of the certification process until the appropriate expert panel from the European Commission expresses an opinion on the relevance of the clinical data.

b) For devices that incorporate medicinal products (pursuant to Regulation 2017/745, Article 52, paragraph 9), Kiwa TR shall analyze the organization's documentation to verify the usefulness of the substance contained in the MD and shall send the results of the analysis to the competent authority selected in agreement with the organization among those designated in accordance with Directive 2001/83/EC.

   Kiwa TR shall not be able to proceed with the certification process until the Competent Authority has expressed a favourable opinion on the matter. In case of a negative opinion, it will not be possible to issue a certificate.

c) For devices based on substances or combinations of substances, which are systemically absorbed by the human body in order to achieve the intended purpose (pursuant to Regulation 2017/745, Article 52, paragraph 11), Kiwa TR shall carry out the analysis of the organization's documentation regarding the compliance of the MD with the relevant provisions set out in Annex I of Directive 2001/83/EC and shall proceed as indicated in point b) above.

4.2 Activation of the certification process

4.2.1 Request for conformity assessment

To access certification services for medical devices (initial certification, extension, or renewal), the Organization must complete the **MDR.FR.018 Information and Application Form** provided by Kiwa TR upon request.

If the Organization chooses to follow the conformity assessment procedure outlined in Annex IX for Class III and Class IIb medical devices, as referred to in Articles 52(3) and 52(4), it must also submit a specific request for the assessment of the technical documentation provided in Section II of Annex IX. This request must include a description of the design, manufacturing, and performance of the medical device.

For Class III and Class IIb medical devices referred to in Article 52(4), Kiwa TR accepts only the certification procedures defined in Annex IX.

Along with the duly completed Information and Application Form, the Organization must also submit the additional documents required by Kiwa TR (particularly those) listed below:

- Certificate of registration at the Chamber of Commerce (copies on unstamped paper) or equivalent document for foreign countries;
- Any quality management system certificates held by the Organisation and its critical suppliers.

4.2.2 Preparation of the offer

Based on the information provided in the Application Form, Kiwa TR prepares a financial offer for CE marking certification, which includes a description of the service to be provided, all relevant details regarding the activities, and the pricing determined according to the applicable fee schedule.

If certain aspects identified in the Application Form indicate that Kiwa TR cannot guarantee its ability to carry out the certification activity, the conformity assessment request will be rejected. The Organization will be informed of the decision along with the relevant justification, and no financial offer will be provided.

For SME's as defined in the European Commission Recommendation 2003/361/EC, the following discounts are applied to the initial certification fee:

15% discount for micro enterprises (fewer than 10 employees*)*

10% discount for small enterprises (fewer than 50 employees)

5% discount for medium-sized enterprises (fewer than 250 employees).

4.2.3 Acceptance of the offer

Acceptance of the offer by the Organisation establishes the contractual relationship between the parties and constitutes the formal request for conformity assessment activities for the purposes of CE marking.

Acceptance of the offer also implies the acceptance of the specifications provided for in this Regulation, in the Kiwa Regulation for Certification and in the General Terms and Conditions document, referred to in the offer itself.

The Customer Organisation may not misuse or misrepresent the trademarks of Kiwa TR and, where applicable, the accreditation body. It may not benefit from certification in a manner that would not be accepted by Kiwa TR or the accreditation body. It agrees to use the logo and trademarks in accordance with the **PR.008 Certificate And Mark Usage Procedure** published on the Kiwa TR website and the TÜRKAK guidelines.

The acceptance of the offer implies that the Organisation must send all of the documentation required in the Annex chosen for evaluation.

Following the acceptance of the offer by the Organization, all Technical Documentation to be must be submitted to Kiwa TR for evaluation within a **maximum of 6 months**.

4.2.4 Review of the offer and order confirmation

Once Kiwa TR has received the offer signed by the Organisation and all the documents requested in the application form, Kiwa TR will review these documents and verify that;

- Have the required data and documents been provided comprehensively?
- Have both parties clearly defined and understood the certification service requirements?
- Does Kiwa TR have sufficient and appropriate resources to carry out the necessary activities?

If the result of the review is positive, the certification process begins.

If the result of the above-mentioned examination is negative, Kiwa TR shall have the right to request the necessary additions or modifications before officially beginning the process or to give notification of the impossibility of beginning it, giving the Organisation the relative reasons.

If the outcome is negative due to technical reasons connected to product safety, Kiwa TR shall be in a position to reject the application for certification, providing the Organisation with the relative reasons and uploading the rejection to the EUDAMED system.

If inconsistencies emerge in the document assessment phase or during the audit with regard to statements made in the application form, the offer may be subject to review by Kiwa TR.

4.2.5 Planning of the conformity assessment activities

The conformity assessment activities include:

1. Documentation analysis,
2. Planned audits at the site/s of the Organisation (as described below) and critical suppliers (if applicable),
3. An unannounced audit,

Depending on the type of request submitted by the Organization (e.g., initial certification, extension, modification, or certification renewal), Kiwa TR determines which conformity assessment activities will be carried out (as specified in the offer) and identifies the human resources to be involved in the process.

The activities can be assigned to employees or qualified external experts in accordance with the requirements of Kiwa TR procedures.

If a situation arises that requires subcontracting of part of the certification process, Kiwa TR shall implement all measures necessary to ensure that the subcontractor complies with the provisions of reference and Kiwa TR system documentation.

Liability for any subcontracted activities remains that of Kiwa TR.

4.3 Analysis of the documentation

The analysis of the technical documentation and of the Quality System documentation is carried out, unless otherwise agreed upon by the parties, at Kiwa TR's premises, by personnel with the necessary technical competence relative to the scheme and type of product to be certified.

Kiwa TR can also establish, in specific cases (for example, risk class of MD, quantity and complexity of the documentation to be evaluated), to do the document analysis at the office of the organization.

The technical documentation includes at least the contents of Annexes II and III of the EU Regulation 2017/745; the quality system documentation includes the contents of Annex IX and Annex XI of the EU Regulation 2017/745.

Documental analysis serves the purpose of checking compliance of the documents relating to the product to be certified with the General Safety and Performance Requirements referred to in Annex I of the Regulation 2017/745.

To ensure safety, Kiwa TR evaluates compliance with the requirements in order to verify that the solutions adopted by the Organization throughout the lifecycle of the certified medical device including transportation, installation, use, and decommissioning meet the minimum necessary requirements.

Personnel must pay particular attention to the solutions adopted during the design, manufacturing, packaging, labelling, and usage processes, and ensure that at least the following minimum conditions are met:

1. All hazards have been identified.
2. All risks associated with the identified hazards have been assessed and included in the overall risk/benefit assessment.
3. All risks have been minimised as much as possible, without any economic considerations.
4. All accepted residual risks are managed through appropriate protective measures, and their reduction is based on genuine safety requirements rather than solely for the purpose of providing information to the market.
5. Security principles have been implemented in accordance with the current level of knowledge and technological developments.

Documents and test reports related to pre-clinical and clinical data will also be subject to verification.

The tests provided by the Organisation must be carried out at external ISO 17025 accredited laboratories, or Testing Centres authorised for Good Laboratory Practices (GLP), or test centres recognised by scientific bodies of proven authority.

The use of other laboratories is accepted in cases where the laboratory has been adequately qualified by the Organisation on the basis of the requirements of ISO 17025 and produces a test report containing the minimum information required by ISO 17025.

Kiwa TR reserves the right to request the performance of other tests, if deemed necessary for the conformity assessment. Any costs associated with the additional tests shall be borne by the Organisation.

Depending on the number of products to be certified or on the homogeneity of the product families, Kiwa TR, at its sole discretion, shall evaluate whether to carry out an analysis of the technical documentation relating to all the MDs subject to certification or whether to carry it out on representative samples for generic groups or sub-categories of products.

The above issue shall not apply to class III and implantable IIb[4] devices, whose technical documents shall always be checked 100%.

The Organisation must keep a controlled updated copy of the technical documentation and of the Quality System documentation for Kiwa TR and make it available during the assessment activities and for the entire period of validity of the assessment contract with Kiwa TR.

Following the completion of the documentation analysis including the evaluation of clinical data and PMCF a report will be issued, accompanied by a conclusion summarizing any potential findings.

The customer undertakes to submit to Kiwa TR, **within 20 days** from the date the findings are reported, a documented plan detailing how the findings will be addressed, including the procedures and documents subject to change. The customer also undertakes to submit the revised documentation, in accordance with the plan, within **a maximum of 90 days.** The closure of the findings will be verified by Kiwa TR through an additional Document Evaluation.

The monitoring of the periods defined above is carried out by the Medical Devices Support Personnel. If the organisation fails to comply with these deadlines, the Medical Devices Support Staff notifies the organisation in writing that the certification activities are not managed as required in the **MDR.GD.001 Regulation For The Certification Of MDs Pursuant To Eu Regulation 2017/745** and that the activity cannot continue and/or the existing certificate will be suspended.

Depending on the result of the analysis of documentation, the Organisation will be able to decide if to integrate or modify the documentation based on the findings or terminate the certification process.

When the Organisation submits the supplementary or amended documentation, another assessment is carried out.

In cases where the resolution of findings identified during the documentation review conducted on-site by Kiwa TR can be easily verified in the next phase, it may be possible to close such findings on-site.

The positive completion of the documentation analysis phase must end within 1 year from the date of the first analysis of the documentation; beyond that limit, Kiwa TR will consider subsequent actions, including a complete re-evaluation of the documentation or termination (withdrawal, refusal, restriction) or interruption (suspension) of the certification process.

These decisions may be taken not only in cases where the time limit is exceeded, but also as a result of significant changes in the regulatory or normative references related to the certified product, or due to any changes in the Organization's processes or operational sites.

If there are significant changes, the maximum time specified above may be reduced at the discretion of Kiwa TR.

4.4 Certification Audit

The certification audit is carried out at the sites where the activities related to the products to be certified take place, with the aim to assess that the quality system verified during the documentary analysis is applied in all of the life cycle phases of the device for which certification is requested. In particular:

- It shall provide for the assessment of all device features with regard to documents and applications;
- It shall provide for quality system assessment regarding the product.

[4] With the exception of suture materials, staples, materials for dental fillings, orthodontic devices, dental crowns, screws, wedges, plates and prostheses, wires, nails, clips, and connectors, which shall be sampled as class IIb. Class IIb implantable devices that are not based on a well-established technology ("Not-WET"), endosseous dental implants, and "abutment" dental implants are excluded from this exception.

The certification audit is planned in accordance with all the requirements of Regulation (EU) 2017/745 on medical devices, based on the selected Annex. The audit must be conducted within a maximum of one year from the start date of the documentation review[5].

After the initial certification site audits carried out before the documentation review is completed, in cases where the documentation review period exceeds 1 year, a special audit of at least 1 man/day is carried out to verify whether the customer organization meets the certification conditions before the certificate is issued. The Planning Responsible is responsible for planning the relevant special audit and communicating with the customer organization.

In defining the aspects to be verified, Kiwa TR decides if any critical suppliers will be audited.

Generally, Kiwa TR may decide **not to** provide audit in the following cases:

1. The supplier has a quality management system certified by an Accredited Certification Body and is effectively controlled by the Organization (e.g., through internal audits). This applies only if the supplied products do not include Class III or innovative devices. Critical suppliers involved in these excluded categories will always be subject to audit.
2. Accredited testing laboratories, test centers authorized under Good Laboratory Practice (GLP), test centers recognized by competent scientific institutions, or laboratories certified for their quality management system by an accredited certification body and controlled by the Organization.

The Lead Auditor prepares an activity plan that is sent to the Organisation.

Any changes to the audit plan may be evaluated and accepted during the opening meeting of the audit, based on the requirements of the Organization.

Where appropriate, the resolution of any irregularities reported in the documentary analysis is also evaluated in the initial phase of the audit. Any unresolved irregularities are included in the audit report as NCs.

Kiwa TR can perform sampling and laboratory tests on the medical device to be certified (see Article 4.5.3).

During the certification audit, the audit plan is prepared by the Lead Auditor. This plan serves as the basis for the subsequent detailed planning of each audit.

At the end of the audit, the Audit Team shall give a copy of the report to the Organisation, who shall sign it.

If any NCs are encountered, the Organisation must send the proposed corrections and corrective actions identified (upon the analysis and formalisation of the root causes that generated them), along with an implementation schedule, to the Lead Auditor of Kiwa TR via the appropriate form within **20 working days** from the date of the audit.

Kiwa TR cannot proceed with the certification approval until receipt of the proposals for resolution and corrective actions are accepted by the Lead Auditor.

The Lead Auditor shall assess the actions proposed; if accepted, they will be communicated to the Organisation.

All non-conformities (minor-major) must be eliminated for the audit to be concluded positively. Corrective actions for non-conformities must be completed within a **maximum of 60 days** from the date of the audit and the relevant objective evidence must be sent to Kiwa. If the manufacturer needs additional time to complete the corrective actions, it must notify in writing, stating the reason for this. The Lead Auditor may grant additional time up to **30 days** by evaluating the request for additional time according to the following criteria.

- The issues that depend on 3rd parties for the elimination of non-conformity have not been completed, (For example, relevant tests, validation studies, training and qualification activities, etc. have not been completed)
- Existence of situations requiring investment (e.g. relocation, construction, equipment, recruitment of new personnel, infrastructure requirements, the need to add new processes or make comprehensive changes to existing processes, etc.)
- Occurrence of extraordinary situations (e.g. sudden deterioration in the health status of the personnel carrying out the activity, change of existing personnel, natural disasters, fire, etc.)
- The need to add new suppliers/raw materials/materials or make extensive changes to existing ones

Evaluation of the corrective actions for nonconformities by the audit team must be completed **within 90 days** from the date of the audit in total, including possible additional requests.

[5] If this time limit is exceeded, Kiwa TR will assess the subsequent actions by taking into account technological developments or changes made by the Organization.

The monitoring of the periods defined above is carried out by the Medical Devices Support Personnel in coordination with the Lead Auditor.

Implementation of corrections and corrective & preventive actions for nonconformities (NCs) cannot begin until the conformity assessment to be carried out by the Lead Auditor is completed. This assessment is conducted either through documentation review or, if necessary, through an on-site audit at the organization's facilities.

The assessment in question must be carried out **within 6 months** following the completion of the certification audit. If this time limit is exceeded, Kiwa TR reserves the right to decide, at its sole discretion, whether to proceed with further actions. If the outcome of the additional assessment is positive, the certification process will continue with the subsequent steps for document approval.

The audit report and any eventual corrective action plan shall be subject to internal analysis and approval by Kiwa TR, for the approval or otherwise of the certificate.

Certification decisions are made by different members with technical and clinical *expertise*, at different times. Members, though in possession of all of the skills and qualifications required by the certification scheme, cannot in any way take part in conformity assessment activities.

During the certificate approval process, members may deem it necessary to request clarification, additional conformity assessment activities or additions from the Audit Team, as well as limitations and/or conditions specific to the certification (see Article 4.9).

Any differing assessments reported by the Audit Team will be communicated to the client.

If the approval process is successful, Kiwa TR issues a declaration of conformity, which is sent to the Organization.

Once the Organization has received CE certification, it applies the notification number 1984 (identification number of Kiwa TR) to the certified devices.

If certification is rejected, Kiwa TR shall send the Organisation a notification specifying the reasons for such denial as established during the certification decision phase and the related actions, for eventually restarting the certification process. The refusal shall be uploaded to the EUDAMED system.

Denial of certification can also occur as a result of negative opinions expressed by other competent Authorities, consulted as required by Regulation 2017/745.

The validity of the certificate is established by Kiwa TR on the basis of the characteristics of the product to be certified (e.g. the risk classification, the clinical evaluation aspects, etc.). However, it cannot exceed 5 years from the date of issue.

4.5 Surveillance Audit

4.5.1 Scheduled surveillance audits

Surveillance audits are performed once every 12 months. They are always carried out at the sites where activities related to products subject to certification take place.

Kiwa TR reserves the right to shorten the standard 12-month surveillance period in cases such as high-risk potential of the devices, suspension of certificates, evaluation of change notifications, adverse event reports, or complaint follow-up etc.

The purpose of the surveillance audit is to ensure that the Organisation applies the approved quality management system and the post-marketing surveillance plan[6], verifies the maintenance of the conditions that led to the granting of certification, as well as any changes to the process or products, if requested in advance (see Article 4.6.1) and approved by Kiwa TR.

Before the surveillance audit, Kiwa TR will request the following updated documents / information from the manufacturer:

- documentation on the quality management system,

- technical documentation of the devices sampled during the conformity assessment (as specified in the certification programme),

[6] The post-marketing plan must be implemented in accordance with Chapter VII and Annexes III and XIV of Regulation (EU) 2017/745.

- Documentation of the findings and conclusions from the implementation of the post-market surveillance plan, including the PMCF plan, and the vigilance provisions set out in Articles 87 to 92,

- PSUR referred to in Article 86 and the post-market surveillance report referred to in Article 85,

- the SSCP referred to in Article 32 of Regulation 2017/745, where applicable.

- number of sites, total number of employees, number of shift workers, number of part-time workers, if applicable, PRRC, management representative

It shall be the responsibility of the Organisation to send the correct and updated documentation to Kiwa TR, according to the minimum time frequencies established by Regulation 2017/745 (based on the type of device subject to certification).

The surveillance audit is based on a sampling of the activities subject to certification, ensuring a complete audit of the management system and of the documentation during the certification cycle.

In addition, the surveillance audit must include the verification of any critical suppliers as defined in the audit programme issued after the certification audit.

During the surveillance audit, the evaluation of the resolution of non-conformities in previous audits is carried out, as well as an assessment of the implementation and effectiveness of the corrective actions taken by the Organisation.

During such audits, Kiwa TR may, if deemed necessary, take samples of certified medical devices and perform laboratory testing (see Section 4.5.3).

For Class III medical devices, components and/or approved materials that are critical to the integrity of the device shall always be subject to testing. Where applicable, the quantities of manufactured or procured parts and/or materials will also be checked for consistency with the quantities present in the finished medical devices.

If Kiwa TR finds a difference between the sample taken from the manufactured devices and the specifications mentioned in the technical documentation, Kiwa TR suspends or withdraws the relevant certificate or imposes reductions/limitations in the scope of the certificate (as applicable).

At the end of the audit, the Kiwa TR Audit Team gives a copy of the audit report to the organization, who signs it.

If the Organization does not provide any notification within **60 calendar days**, the report shall be considered confirmed.

In the event of any nonconformity (NC), the Organization must submit the proposed corrections, the defined corrective actions (based on root cause analysis and formalization), and the corresponding implementation plan to the Kiwa TR Lead Auditor within **20 working days**, using the appropriate form.

The Lead Auditor evaluates the proposed corrective actions; if accepted, the Organization will be notified **within 30 calendar days**.

All non-conformities (minor-major) must be eliminated for the audit to be concluded positively. Corrective actions for non-conformities must be completed within a **maximum of 60 days** from the date of the audit and the relevant objective evidence must be sent to Kiwa. If the manufacturer needs additional time to complete the corrective actions, it must notify in writing, stating the reason for this. The Lead Auditor may grant **additional time up to 30 days** by evaluating the request for additional time according to the following criteria.

- The issues that depend on 3rd parties for the elimination of non-conformity have not been completed, (For example, relevant tests, validation studies, training and qualification activities, etc. have not been completed)
- Existence of situations requiring investment (e.g. relocation, construction, equipment, recruitment of new personnel, infrastructure requirements, the need to add new processes or make comprehensive changes to existing processes, etc.)
- Occurrence of extraordinary situations (e.g. sudden deterioration in the health status of the personnel carrying out the activity, change of existing personnel, natural disasters, fire, etc.)
- The need to add new suppliers/raw materials/materials or make extensive changes to existing ones

Evaluation of the corrective actions for nonconformities by the audit team must be completed **within 90 days** from the date of the audit in total, including possible additional requests.

The monitoring of the periods defined above is carried out by the Medical Devices Support Personnel in coordination with the Lead Auditor.

Implementation of corrections and corrective & preventive actions for nonconformities (NCs) cannot begin until the conformity assessment to be carried out by the Lead Auditor is completed. This assessment is conducted either through documentation review or, if necessary, through an on-site audit at the organization's facilities.

The assessment in question must be carried out within 6 months following the completion of the surveillance audit. If this time limit is exceeded, Kiwa TR reserves the right to decide, at its sole discretion, whether to proceed with further actions.

If the above assessment is positive, certification is confirmed.

If the Organization fails to implement the agreed actions for the resolution of nonconformities within the specified timeframes, the certification may be suspended.

For Major NCs that can affect product safety, certification shall be suspended until the resolution of NCs is verified (or for potential cases, reduced).

The performance of surveillance audits during the certification cycle is subject to the regular payment of invoices for previous activities by the Organisation.

Conversely, Kiwa TR reserves the right not to carry out the planned activities and proceed with certificate suspension or withdrawal.

4.5.2 Unannounced Surveillance Audit

Kiwa TR conducts unannounced audits at least once every five years at the facilities where activities related to the certified products are carried out (including those of critical suppliers and/or the authorized representative) in order to verify continued compliance with quality management system requirements.

Kiwa TR may increase the frequency of audits without prior notice in cases where devices pose a high risk, are generally non-compliant, or there are specific reasons to suspect non-conformity related to the devices or the Organization.

The Organization agrees to inform Kiwa TR about periods during which the production of certified medical devices does not take place (e.g., company shutdowns, holidays, production interruptions, etc.) to ensure the proper execution of unannounced audits.

In addition, in agreements governing the relationship with its critical suppliers, the Organisation agrees to include prior authorisation for Kiwa TR to access the premises/sites where the critical supplier carries out its activities.

In cases where a visa is required to carry out the on-site audit at the supplier’s premises, the Organisation must provide an invitation letter with open (signature and visit) dates.

Moreover, critical suppliers must agree to provide the organization, which in turn shall promptly inform Kiwa TR, with information on the periods of the year (company closures, holidays, production stoppages, etc.) during which the latter do not provide their business activities on behalf of the organization.

The Kiwa TR Audit Team visits the sites where activities related to the certified products are conducted, presenting official assignment letters.

The Organisation can contact Kiwa TR’s offices and request confirmation of the activities.

During unannounced audits, Kiwa TR may perform checks through testing on an appropriate sample, preferably taken from the ongoing production process, to assess compliance with technical documentation and legal requirements.

If a difference between the sample taken from the manufactured devices and the specifications mentioned in the technical documentation is found, Kiwa TR suspends or withdraws the relevant certificate or imposes reductions/limitations (as applicable).

In the event that the organization (or its critical suppliers) refuses to undergo an unannounced audit, this decision must be formally documented. The document should be prepared on the organization's letterhead, stamped and signed, and must clearly state the reasons why the audit could not be conducted.

Kiwa TR reserves the right to evaluate subsequent actions that may lead to the suspension or withdrawal of the certificate. The organization will be promptly informed of any decisions made.

In the event of lack of access to the Organisation’s premises (or of those of critical suppliers) during an unannounced audit, Kiwa TR shall be entitled to terminate the agreement and withdraw the certification.

If deemed appropriate by both Kiwa TR auditors and the organization, the unannounced audit may be combined with a scheduled surveillance audit.

At the end of the unannounced audit, the Lead Auditor provides a copy of the audit report to the organization. Additionally, a copy of the records of the tests conducted on the audit day compiled by the authorized personnel responsible for testing within the organization and/or its critical supplier is filed.

If the tests are carried out by an external laboratory or the test results require longer time frames than the days of the audit, the report will only be closed by the Lead Auditor after the outcome of the tests, which is sent to the organization together with the test reports from the external laboratory.

If the Organisation desires, a copy of the completed report can be issued.

The management of the results of the unannounced audit occurs according to the same method described in Article 4.5.1.

4.5.3 Product testing activities

The tests referred to in the previous paragraphs shall be carried out for all medical devices, with the exception of class III implantable devices, according to the test procedure specified by the organisation in the technical documentation and can be performed:

- At the premises of the organization or its critical supplier, it is assessed whether the tests conducted by authorized personnel under the supervision of the Audit Team are performed in appropriate environments and whether the measuring instruments used have been calibrated by accredited calibration laboratories, thereby ensuring metrological traceability.
- at Kiwa TR Laboratory or with external laboratories qualified by Kiwa TR.

If an external laboratory is used, the samples must be packaged and sent to the laboratory by the Organisation, as specified by the Lead Auditor, ensuring the integrity of the packaging of the samples, without any alteration of the same.

4.5.4 Samples from the market

Kiwa TR reserves the right to test the product, also after taking a sample of medical devices from the market.

This can occur if, for example, during the unannounced audit there are not any products to sample or in any other phase of the certification process in the event of complaints, reports, or cases of suspected product non-conformities, etc.

The applicable procedures for carrying out tests and the management of results follow that already described in the previous paragraph.

4.6 Changes or Extensions

4.6.1 Changes

The Organisation must inform Kiwa TR in advance in relation to the following changes:

- changes to the approved [7]quality management system or to the range/type of certified products;
- changes to the design[8] and to the software, approved for the device;
- changes to the intended use, to the conditions of use and to the *claims* attributed to the device;
- changes to any substance inserted or used for the manufacture of the device, with particular reference to medicinal substances, tissues or cells of animal origin and their derivatives, other substances referred to in the specific procedures of Annex VII point 4.5.6 of Regulation 2017/745;
- administrative changes such as, for example, a change in the company name.
- company-related changes such as, for example, mergers, demergers, business lease agreements.

Any requests for changes must be sent to Kiwa TR in writing, attaching the plan of changes and the related detailed information.

[7] For example: production processes and technologies, human resources or equipment used, changes to production sites, changes to critical suppliers, change of ownership/Legal Representative, change of the person responsible the release of the product or the person responsible for compliance with applicable legislation.
[8] including materials, packaging, safety and performance requirements.

On the basis of the information and documents received, Kiwa TR shall assess the significance of the changes communicated on a case-by-case basis, also taking as reference the documents issued by the Medical Device Coordination Group (MDCG), and shall establish the consequent actions (including documentary and/or on-site assessments, as described in the previous paragraphs), which shall be formally communicated to the organization. It shall not be possible to process requests for changes that have not previously been communicated during periodic audits at the organization's premises.

The Organisation shall not be able to implement any changes before receiving Kiwa TR's formal approval.

4.6.2 Extensions

Any extension related to products, sites, or the content of the certificate shall be considered an extension of the certificate.

The organization must inform Kiwa TR in advance in case of extensions to the certification, following the procedure previously described starting from Article 4.2.1. It shall not be possible to process requests for extensions during the periodic audits carried out at the organization's premises.

Based on the type of extension requested, Kiwa TR shall establish the correct certification procedure as described in Article 4.2 to Article 4.4 (for the applicable parts).

The expiry date of the certificate cannot be changed, even if the certificate is extended.

4.7 Recertification Audits and Certificate Renewal

At least 6 months before the expiry of the certificate, Kiwa TR must perform an audit for the renewal of the certificate, which aims to facilitate an effective review, including at a documentary level, of the conformity of the products to be certified.

The certification renewal audit follows the same rules indicated for the initial certification audit (including the documentary analysis).

Before the renewal audit Kiwa TR shall request the following updated documents: technical documentation, evaluation reports of clinical data (including post-marketing surveillance and *post-marketing clinical follow-up data* (PMCF)), PSUR and PMSR, and where applicable the Summary of safety and clinical performance (SSCP) in accordance with Article 32 of Regulation 2017/745.

Upon renewal, the performance of the management system in the previous certification cycle shall be reviewed.

During the renewal audit, the organization is required to submit a summary of scientific findings and changes related to the certified device. This summary must include, at a minimum, the following:

a) all changes to the originally approved device, including those not yet notified*;*

b) experience gained from post-market surveillance activities;

c) experience from risk-management activities*;*

d) experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I of Regulation 2017/745;

e) experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF;

f) changes to the requirements, to components of the device or to the scientific or regulatory environment;

g) changes to harmonised standards, applied or new ones, to *Common Specifications* or to equivalent documents;

h) changes in medical, scientific and technical knowledge, such as:

- new treatments,
- changes in test methods,
- new scientific findings on materials and components, including findings on their biocompatibility,
- experience from studies on comparable devices,
- Data from registries (entities/organisations) and clinical data records (e.g. national or international implant or treatment databases),
- experience from clinical investigations with comparable devices,

Management of the renewal audit results shall take place according to the same method described in Article 4.4.

Where it is not possible to close a Major NC by the expiry of the certificate, the renewal must take place within the subsequent 6 months.

After this deadline, Kiwa TR must reject the renewal application, uploading it to the EUDAMED system and sending communication to the Organisation in this regard.

An organisation that wishes to regain EU certification shall have to initiate a new certification process.

In cases where the renewal is not completed by the time the certificate expires, the products may not display the reference to the certification and may not be placed on the market with the CE marking no.1984.

The execution of a renewal audit is subject to the regular payment of the aforementioned activities by the Organisation. Otherwise, Kiwa TR reserves the right not to perform the activities planned for the renewal.

4.8 Other conformity assessment procedures

Importers, distributors and other physical or legal entities who carry out the activities referred to in Article 16 point 2 of Regulation 2017/745, must submit an application to Kiwa TR for certification of the quality management system as required by Article 4.2.

Kiwa TR shall directly carry out the certification audit and the consequent activities, as provided for in Article 4.4., limiting the evaluation to aspects relating to the quality management system, with particular reference to the existence of procedures that guarantee:

- an accurate and updated translation process of the information provided with the MD,
- that supply activities pertaining to all the information necessary to market the MD and changes to the outer packaging, are carried out with means and based on conditions that preserve the original state of the MD,
- that the packaging is not defective, of poor quality or untidy;
- that the manufacturer of the MD provides notice, on an ongoing basis, of any corrective actions taken for the compliance of the MD,
- that the packaging of the MD or an accompanying document provides information relating to the activity carried out together with the company name or registered trademark, the registered office, and the address where the latter can be contacted.

The activities concerning the surveillance and renewal of the certification shall follow the specifications set out in Article 4.5 to Article 4.7 and shall be aimed at evaluating the aspects described above.

4.9 Additional Evaluations

In addition to the provisions of the normal certification process, described in the previous paragraphs, Kiwa TR reserves the right to perform other additional assessments (both documentary and on-site).

Additional or supplementary audits can even be carried out at short notice (**5 working days from the date set for the audit**).

In this case, considering that it may not be possible for the organization to reject the audit team members appointed by Kiwa TR, maximum attention shall be paid to the selection of the audit team.

The need to carry out these assessments may be due to:

- reasons outlined in the Kiwa Certification Regulations
- requests arising during the Certification Decision phase;
- the need to authorise the placement on the market of products in the warehouse;
- In case of information received pertaining to serious accidents, emergencies or malfunctions;
- In case of reports or notices received regarding non-conforming aspects related to certified medical devices.

Additional assessments are charged to the organization; they do not replace or modify the procedures and frequency of periodic surveillance assessments and are communicated to the organization in advance.

In the event of unavailability of the Organisation to carry out those activities, Kiwa TR reserves the right to suspend or revoke (in cases considered more serious) the certification issued.

4.10 Specific Conditions

Depending on the type of device (innovation, risk class, etc.), Kiwa TR reserves the right to establish limitations or specific conditions for certification at any stage of the process, formally communicating them to the organization.

These specific conditions may include changes to the rules of the standard procedure set out in the previous paragraphs, such as, for example, limitations on the validity of the certificate issued, the intended use of a device for certain groups of patients, different frequencies of conformity assessments (e.g., for the evaluation of clinical data), and specific post-marketing clinical follow-up studies in accordance with Annex XIV, part B of Regulation 2017/745.

5. CHANGE OF NOTIFIED BODY

5.1 General Requirements

An Organisation that wishes to change the Notified Body, must send a formal application to Kiwa TR.

The procedure for the transfer of the certification from the outgoing Body to Kiwa TR shall always be agreed upon with the Organisation during the offer phase and, for the purpose of issuing the certificate, compliance with the provisions set out in Article 4.2 to Article 4.4 shall be required.

In addition to the required documentation identified in the aforementioned paragraphs, upon receipt of the accepted offer, Kiwa TR shall also request the following documents:

1. A copy of the complete audit reports for the first certification (or the last renewal) and the last surveillance report, conducted by the former Notified Body.
2. A copy of the complete document assessment reports for the first certification (or the last renewal) and the last surveillance, including evaluations of clinical and post-marketing data (including PSUR, PMCF, PMSR and SSCP), for all certified products.
3. Any documentation outlining the management (treatment, corrective actions) of NCs identified;
4. Complaints received, data related to audits and evidence of their management;
5. The audit plan of the former Notified Body;
6. A copy of EU certificates issued by the former Notified Body;
7. A copy of quality system certificates or EU certificates (if any) for critical suppliers;
8. Communication to Kiwa TR of residual lots marked with the number of the former Notified Body;
9. *Labelling* of products certified by the former Notified Body and drafts of the new labelling;
10. Declaration of conformity of certified products by the former Notified Body and drafts of the new declaration.

5.2 Voluntary change of Notified Body

The voluntary change of the notified body is managed by Kiwa TR in compliance with the provisions of Article 58 of EU Regulation 2017/745.

In particular, Kiwa TR will ask the Organisation (or its authorised representative) to sign the **S.M.FR.026 Transfer Agreement that** details the provisions of the aforementioned Article.

The certification transfer activity (issuing the certificate) can only be completed when Kiwa TR is certain that the previous EU certificate has been revoked, through notification from the former Notified Body (where possible) regarding the revocation of the existing EU certificate.

5.3 Forced change of Notified Body

The forced change of the notified body shall be managed by Kiwa TR under the conditions set out in Article 46 of Regulation (EU) 2017/745 in the following cases.

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1. voluntary cessation of conformity assessment activities by the former Notified Body,
2. revocation of the designation by the Competent Authority, which has also formally confirmed that the certificates have not been unduly issued and there are no problems in terms of the safety of the MD's

Kiwa TR shall assume responsibility for the EU certification, if it decides to accept the change of Notified Body request.

This responsibility shall be assumed **for a maximum period of 9 months** in the case referred to in point 1 and **12 months** in the case referred to in point 2. during this period, Kiwa TR shall conduct the entire assessment process as provided for in Article 5.1 for the purpose of issuing the new certificate.

In the case of suspension or temporary limitation of the designation by the Authority responsible for another Notified Body, if the responsible Authority establishes that the other Notified Body does not have the capability to maintain the certificates in force and if Kiwa TR decides to accept the Organisation's request, Kiwa TR shall temporarily take over responsibility for surveillance activities pertaining to the EU certification for the suspension or limitation period set by the responsible Authority.

In this case, Kiwa TR shall formulate an offer that includes the activities required for monitoring the EU certification, depending on the stages of the process corresponding to the certificates to be monitored.

6.SUSPENSION, CANCELLATION OR REDUCTION OF THE CERTIFICATION

Certification can be suspended, withdrawn or reduced for the reasons indicated in the *Kiwa Regulation for Certification*, on request by the Organisation, or in the following additional cases:

- Serious reports from the market and/or Competent Authority, failure to promptly notify Kiwa TR regarding actions of any kind by the public authority, and/or accidents or legal proceedings in progress;
- Implementation of significant changes to the approved product or quality management system, without informing Kiwa TR in advance and approval by Kiwa TR;
- References to certification or use of Kiwa TR mark in such a manner as to deviate from the provisions of this Regulation;
- Incorrect designation (the product cannot be categorised as a MD) or misclassification of MDs*;*
- Bankruptcy or cessation of activity.

In the event of suspension/withdrawal/reduction, Kiwa TR shall notify the Organisation in writing, communicating the conditions that could be met.

Based on the reasons that led to the suspension/withdrawal/reduction, Kiwa TR reserves the right to*:*

- Request the Organisation to recall the products already placed on the market;
- In cases of suspension, if the organization submits a notification signed by its legal representative identifying the relevant product lots/parties in stock, it is permitted to continue marketing products that were already manufactured and placed on the market as of the suspension date, for **a period of six months** from the date of suspension;

In this case, Kiwa TR reserves the right to conduct an audit at the Organisation's premises before providing approval for the products to be placed on the market. The cost of the audit in question will be covered by the Organization.

For cancellation or reduction cases, the Organisation must communicate the last lot sold at the time of revocation or reduction. Products in stock with certification mark no. 1984 can no longer be sold.

During the suspension period, the Organisation loses the right to refer to the certification and use the CE 1984 marking and relative certificate and must stop using all advertising material that contains relative references and return any certification documents to Kiwa TR upon request.

The conditions for reinstatement of the certificate (including the activities of the conformity assessment) shall be established by Kiwa TR according to the reasons that led to the suspension and based on the duration of the suspension.

Except in exceptional cases (approved by Kiwa TR or by the Competent Authority), the period of suspension may **not last longer than 6 months**.

In the event that the Organisation fails to implement the actions indicated by Kiwa TR for the purpose of reinstatement the suspended certification, the latter shall be withdrawn or, where possible, its scope shall be reduced.

The reduction of the scope of application of the certification involves modifications to the certificate, specifying the type of product for which the certification is still valid.

The withdrawal of the certificate determines the automatic resolution pursuant to the Turkish Trade Code of the agreement to which this Regulation applies, except, in any case, the compensation of any damages suffered by Kiwa TR.

Following certification withdrawal, the Organisation loses the right to refer to the certification and use the CE 1984 marking and the related certificate. The Organisation can start the certification procedure again by submitting a new application.

The suspension, withdrawal and reduction of the certificate are communicated by Kiwa TR to the Competent Authority using the EUDAMED system, with information concerning the reasons and medical devices to which it applies.

Kiwa TR reserves the right to communicate the suspension, reduction or withdrawal to third parties that may request it.

7.INCORRECT USE OF CERTIFICATION, THE CERTIFICATE AND CE MARK

The Organisation must use the CE mark as defined in Annex V of the EU Regulation 2017/745.

The following rules below apply in addition to that indicated in the Kiwa Regulation for Certification.

It is considered incorrect use of the certification or certificate when a third party is misled, or led to misinterpret the nature, quality and origin of the device.

In particular, it must be clear that the certification relates solely to the “product” certified. Partial copies of the certificate are not allowed.

The CE marking is used incorrectly if:

- The marking is applied to devices that are not compliant with the scope described in the certificates;
- The certificate has expired and has not been renewed;
- The devices refer to certification not yet requested or denied;
- The devices have certification that has been withdrawn/suspended/reduced;
- The Organisation has not implemented the changes requested by Kiwa TR.

If incorrect use of the certification, certificate or CE marking is found, Kiwa TR withdraws the certification and notifies the Competent Authority.

In severe cases (such as unlawful marking, fraudulent use) Kiwa TR shall also provide notice to the Turkish Public Prosecutor.

8.COMPLAINTS, APPEALS AND DISPUTES

8.1 Complaints

The Organization may present documented complaint regarding its dealings with the certification activities provided by Kiwa TR.

The complaint may arise from problems encountered during the certification process, such as delays in completing the various phases and/or incorrect conduct by staff who performs Kiwa TR conformity assessments.

Complaints must be submitted in written form; any format (e.g., email, letter, form) is acceptable, provided the situation is described in detail.

Kiwa TR records all complaints, examines them, and informs the claimant of the actions taken **within 60 days** of receiving the complaint.

Kiwa TR will establish with the claimant whether and to what extent the content of the complaint and its resolution should be made public.

A detailed description of how to lodge complaints is available on the https://www.kiwa.com/tr/tr website.

8.2 Appeals

If the claimant is not satisfied with the response received, or intends to appeal against the decision of Kiwa TR, it can present an appeal in writing.

The petitioner must state the grounds for its appeal and, where the appeal refers to a decision made by Kiwa TR, it must be presented to Kiwa TR **within 10 calendar days of** the decision being communicated.

Kiwa TR will give the petitioner a written reply and will give notification of any actions to be taken **within 120 days** of the date of receiving the appeal.

A detailed description of how to make appeals is available on the https://www.kiwa.com/tr/tr website.

8.3 Disputes

If the result of the appeal is not accepted by the complainant, any dispute between the Organisation and Kiwa TR shall be managed in compliance with Article 18 paragraph 1 of the *General Terms and Conditions of Kiwa TR for the performance of orders*.

9.UNILATERAL CHANGE OF THE CONTRACT

Kiwa TR reserves the right to modify this Regulation at any time. Any new clauses/changes shall be effective from the time they are communicated to the Organisation in writing.

Any organisation that does not intend to accept the changes may withdraw from the contract by giving written notice by registered letter with return receiptor or by certified mail within 30 calendar days from the day following the communication to Kiwa TR, under penalty of forfeiture.

The withdrawal shall be effective from the last business day of the month the Organisation receives the notice.

10. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT

Kiwa TR may freely withdraw from the Agreement with the Organisation by giving written communication to the Organisation with a notice of **6 months** from the effective date of withdrawal.

The withdrawal by Kiwa TR determines the withdrawal of the issued certification. The Organization is in any case obliged to pay Kiwa TR the amounts due for the services received during the notice period, as established in the last valid quotation.

If the Organisation wishes to terminate the contract, unilateral withdrawal during the period of Certification validity requires compliance with the notification time frames established in the *General Terms and Conditions* and *the Kiwa Regulation for Certification*.

If notification is provided less than three months but more than two weeks before the scheduled audit date, the organization is required to pay **50% of the cost** foreseen for the related activity as specified in the Agreement.

For periods of notice of **less than two weeks,** the conditions specified in the *General Terms and Conditions* shall apply.

Kiwa TR will issue an invoice for the expenses of closing the certification file, in accordance with the last valid quotation.

ANNEX-A Documents to be submitted by the manufacturer to KIWA TR

Techical Documentation

Device Description and Specification

General description, including intended purpose and intended users (MDN, MDA, MDS codes (refer to MDCG 2019-14)) as well as information on whether the device is for single use only, multiple use, reprocessing, and its number of cycles (including description of packaging).

Clear identification of device by unambiguous reference allowing traceability.

Basic UDI-DI (Additional guidance on Basic UDI-DI may be found in the MDCG documents published on the EU Commission website.) EMDN code (European Medical Device Nomenclature (EMDN code) shall be identified; refer to guidance published on the EU Commission website).

The intended patient population and the medical condition(s) to be diagnosed, treated, and/or monitored, including relevant details such as patient selection criteria, indications for use, contraindications, and any applicable warnings.

Principles of operation of the device and its mode of action, scientifically demonstrated if necessary.

Rationale for the qualification of the product as a device, justification for the risk class and classification rule (Annex VIII, Chapter III).

Explanation of any novel features.

Description of all accessories/product intended to be used with the device.

Description of all configurations/variants of the product.

General description of key functional elements (parts/components, formulation, composition, functionality and, where relevant, qualitative and quantitative composition).

Mechanical drawings, photographs.

Electrical circuits, block diagrams.

Raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body.

Technical specifications as typically claimed in e.g. catalogues, brochures (e.g. features, dimensions, performance attributes, etc.) of the device and the accessories.

Previous and Similar Generations of the Device

Previous generation produced by the manufacturer

Similar devices available on the Union or International market

Labelling

Complete set of labels (as on the device, on the (e.g., single unit) packaging, sales packaging, and transport in case of specific conditions).

Instruction for use (IFU)

Electronic Instructions for Use

Implant card and information to be supplied to the patient with an implanted device

Design and Manufacturing

Information on design stages applied to the device

Manufacturing processes, their validation, their adjuvants (including identification of the respective manufacturing line)

Complete specifications (product specification, packaging specification, incoming inspection, continuous monitoring, in process controls, final product testing, installation specification)

Site(s), including subcontractor(s), supplier(s) where design and manufacturing activities are performed

In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps.

General Safety & Performance Requirements

“General safety and performance requirements” document

Benefit-Risk Analysis and Risk Management

Risk Management

Risk management plan

Risk assessment including risk control

Information from the production phase and PMS on hazards and the frequency of their occurrence, risk acceptability, including possibly the adaptation of control measures.

Overall residual risk evaluation including residual risk evaluation

Usability Evaluation

Pre-Clinical (Product Validation/Performance) Data

Test laboratory accreditation (GLP/EN ISO 17025)

Evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications

Chemical characterization

Biocompatibility, including identification of all materials in direct or indirect contact with the patient and user, and biological/chemical tests/studies in animal models.

Performance and safety (physical/ mechanical tests)

Electrical safety and electromagnetic compatibility

Software verification and validation including information on all of the different hard- ware configurations and, where applicable, operating systems identified in the information supplied by the manufacture

Simulated use testing/testing in animal models

Shelf Life / Transport Simulation

Product and packaging stability Tests, (up to the claimed shelf life)

Transport evaluation/validation (product and packaging)

Specific Cases – Devices Incorporating a Substance Considered to be a Medicinal Substance

Medicinal substances

Source of medicinal substance (including manufacturer)

Drug Master File (DMF) (available for review)

Test(s) conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device

Usefulness of the substance as part of the device, taking account of the intended purpose of the device

Specific Cases – Devices Incorporating Materials to be Absorbed by or Locally Dispersed in The Human Body

Materials intended to be absorbed by or locally dispersed in the human body

Absorption, distribution, metabolism and excretion tests

Possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions

Local tolerance

Toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device.

Justification in case above mentioned studies on absorbable or locally dispersed materials are not performed/provided

Specific Cases – Devices Incorporating Substances which are CMR or Endocrine Disrupting Substances

Substances which are carcinogenic, mutagenic or toxic to reproduction (CMR) and/or endocrine disrupting substances

CMR concentration above 0.1 % weight by weight (w/w) where justified pursuant to Annex I, point 10.4.2

Specific Cases – Devices with a Measuring Function

Devices with a measuring function including evidence of accuracy as specified

Specific Cases – Combination and Connection to Other Devices

Accessories, detachable parts, and other devices required for the intended operation of the device must be supported by evidence demonstrating the safety and performance of the combination.

Specific Cases – Sterile Devices or Devices in Defined Microbiological Condition

Microbiological characterization: bioburden testing, pyrogen testing

Packaging validation (for sterile devices)

Description of sterilization method (including location)

Validation of sterilization method

Testing for sterilant residues

Usage of preservatives

Reprocessing / sterilization before use

Aseptic filling / sterilization filtration

Clinical Data

Clinical evaluation report and clinical evaluation plan

Clinical investigation

Outcome of the Clinical evaluation consultation/ notification (Class III implantable devices / Class IIb active devices intended to administer and/or remove a medicinal product, as classified under Rule 12) (MDR Article 61, #2)

Summary of Safety and Clinical Performance (SSCP) (SSCP for implantable devices and class III devices)

Post Market Surveillance

PMS plan

Post-market clinical follow-up plan and evaluation report (update of clinical evaluation)

Periodic Safety Update Report (PSUR) (PSUR for class IIa, IIb , III)

EU Declaration of Conformity

EC Declaration of Conformity

Quality Management System Documentation

Documentation on the quality management system such as quality programs, procedures, quality plans and quality manuals including / addressing;

- a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system
- identification of applicable general safety and performance requirements and exploration of options to address those requirements
- responsibility of the management,
- resource management, including selection and control of suppliers and sub-contractors;
- verification of the UDI assignments made in accordance with MDR Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with MDR Article 29
- a documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under the MDR and the undertaking by the manufacturer in question to apply those procedures,
- a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,
- the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in MDR Articles 87 to 92
- a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in MDR Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures,
- the manufacturer's quality objectives

- the organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority
- Procedure for the management of documents and of records pertaining to the manufacturer's quality system, including the technical documentation
- Procedure designed to identify the measurable objectives of the quality management system at all levels, and which describes the relative methods, responsibilities and frequencies for their control and periodic review
- Procedure for the internal control of processes relating to the quality management system (audit), describing the relative methods, responsibilities and frequencies
- Procedure for the management of corrective and preventive actions, describing the relative methods, responsibilities and frequencies
- processes for monitoring and measurement of output, data analysis and product improvement
- Procedure for the management of communications with the Competent Authorities (CA), Regulatory Bodies, Notified Bodies and the European Commission in reference to all those registration, surveillance and market surveillance activities
- Procedure that manages the strategy for the identification of the relevant mandatory documents applicable to the product (rules, guidelines, CSs, etc.), their impact on the quality management system and on documents and their correct updating, on a continuous basis, in case of changes.
- Procedure for Risk Management
- Procedure for planning, developing, documenting and controlling the design process associated with the device(s)
- Procedure for handling changes that have an impact on the design and manufacture of the device(s)
- Procedure designed to ensure that the products/services supplied comply with what has been defined in the technical documentation
- Procedure for planning, executing, monitoring, verifying and documenting production activities
- Procedures for process monitoring and measurement during production
- Procedure for the management of non-conforming products (identification, isolation, treatment, disposal, reprocessing)
- Procedures for the repackaging and relabelling of devices already on the market, carried out by economic operators referred to in Article 16, point 2 adequately documented, providing a link with the original device
- Procedure for planning, conducting, verifying, documenting and where appropriate, updating pre-clinical assessment
- Procedure which specifies the methods for planning, conducting on an ongoing basis, evaluating, documenting, transmitting and updating clinical data relating to the device, which provides sufficient clinical evidence to confirm the general safety and performance requirements under normal conditions as provided for in Annex I, points 1 and 8, as well as the evaluation of undesirable side-effects and the acceptability of the risk-benefit ratio.
- Procedure for planning, establishing, documenting, implementing, maintaining and updating an active post-market surveillance system (PMS) in a manner that is proportionate to the risk class and appropriate for the type of device
- Procedure that describes the approaches adopted by the manufacturer to meet specific requirements applicable to the information to be supplied with the device, as required in Annex I, chapter III