STATUS OF REVISIONS		
Rev.	SUMMARY OF CHANGES	DATE
4	Clarifications regarding the Manufacturer's signature on the contract, definition of the deadline for submitting the certification renewal application, minor modifications to the change management, contradictory procedure and definitions of suppliers.	2024-09-27
3	Clarifications and additions to conformity annexes, introduction of classification of findings for document analysis, modification of rules for NB change, other minor changes.	2022-03-04

VERIFICATION	Management System Compliance Manager Dr. Alessandra Zazzera
APPROVAL	Compliance and Legal Affairs Director Ing. Maria Anzilotta

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1. SCOPE AND FIELD OF APPLICATION

This Regulation define the rights, duties and operational methodology that govern the relationships between Kiwa Cermet Italia S.p.A. (hereinafter referred to as "Kiwa Cermet") and the Organisation[1] (hereinafter also referred to as "Customer"), in implementation of the procedures to be used for the assessment of conformity of medical devices[2] (hereinafter also referred to as "MD"), provided for in Regulation (EU) 2017/745 and subsequent amendments (hereinafter also referred to as MDR).

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 these RG 01 MED_MDR Regulations form an integral part of the contract entered into with Kiwa Cermet (economic quotation, *Kiwa Regulations for Certification* and *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders* - hereinafter referred to as *General Terms and Conditions).* These requirements refer solely to the aspects specifically connected with the scope of the requested certification.

In case of discrepancy between the Italian version and the English version of any documents relevant to the certification procedure, the Italian version shall prevail.

The types of MDs for which Kiwa Cermet is authorised to operate, are set out in the notification issued to Kiwa Cermet by the Appointing Authority[3].

For the purposes of interpreting this regulation, the following definitions shall apply in relation to any third parties providing a product or service in relation to the MD subject to certification:

- "**Supplier**": Organization or legal entity external to the customer providing a product or service related to the MD subject to certification that does not affect the safety and performance of such MD;
- "**Critical supplier**": Organization or legal entity external to the Customer that provides materials, components or services that have a significant impact on the design and production processes of the MD subject to certification, in terms of safety and performance (e.g. design, custom components, special processes, critical raw materials, crucial semi-finished products, etc.). Among these suppliers, downstream sub-suppliers shall also be included if considered critical in relation to the above.

The contract expressly excludes any form of consultancy to the Organisation that could jeopardise the nature of independence of the audits.

2. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER

In its conformity assessment activities, in addition to what is provided for in the *General Terms and Conditions*, Kiwa Cermet applies the following principles and commitments:

a) Non-discrimination: certification services are accessible to any Organisation requesting them, in accordance with this Regulation, without any discrimination of a commercial or financial nature or regarding membership of particular associations.

b) Impartiality and independence, ensured by suitable measures, including:

- On time implementation of formalised rules and procedures in use by all personnel certification and periodic consultation with certification stakeholders;
- Certification activities are assigned to personnel who do not have a vested interest in the Organisation subject to certification, who are held to observe the rules of conduct and independence established by Kiwa Cermet. As such, Kiwa Cermet agrees to accept any justified concerns of the Organisation, within 3 working days of the notification of the nominations, concerning the existence of incompatibility of the duty assigned that could compromise the impartiality or independence of judgment;
- Clear separation between the personnel carrying out the audit and personnel responsible for certification decisions;

[1]The term *Organisation* means any "economic operator", as defined in Article 2 point 35 of Regulation (EU) 2017/745, to which this Regulation applies. For Kiwa Cermet, 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 Regulation (EU) 2017/745 apply.

[3] In accordance with the reference legislation "**Appointing Authority**" means the authority or authorities designated by a Member State to assess, designate, notify and monitor Notified Bodies: https://ec.europa.eu/growth/tools-databases/nando.

- Total abstention from the performance of consultancy activities in the definition and application of the requirements for obtaining the Certification.

c) Prompt management of complaints, appeals and disputes, as defined in § 9 of the 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. Kiwa Cermet requires all of its personnel, including those performing conformity assessments, to sign a confidentiality agreement and a document in which they commit to treat any information that comes into their possession in accordance with the provisions of the Privacy Act;

A similar commitment concerning the confidentiality is guaranteed by Control Bodies and Competent and Designating Authorities, to which Kiwa Cermet must guarantee access to Customer data. Information exchanged confidentially between Competent Authorities and the former as well as the European Commission are 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 Cermet undertakes to inform the Organisation of any rejection, reduction, suspension or withdrawal of the accreditation and/or ministerial notification; in such cases Kiwa Cermet will be in no way responsible for any damages caused to the Organisation by rejection, reduction, suspension or withdrawal of the notification; in the aforementioned cases, the Organisation has the right to opt out of the contractual relationship with Kiwa Cermet, without the need for prior notification and without any additional costs. If the designation has been suspended, reduced or withdrawn, Kiwa Cermet 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 Cermet decides to cease conformity assessment activities, it will inform the responsible authority of the notified bodies and the manufacturers concerned as soon as possible and, if the cessation 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 Cermet), for a temporary period of nine months after Kiwa Cermet 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 Cermet 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 Cermet agrees to inform the Organisation as regards subcontractors used.

3. ACCESS REQUIREMENTS FOR CERTIFICATION

3.1 General Obligations of the Organization

In addition to the provisions of the *General Terms and Conditions and the Kiwa Regulation for Certification*, the Organisation (or its representative) must in the certification application phase, commit to comply with the following obligations:

- Accept the conditions set out in this Regulation which is also available on the Kiwa Cermet website (www.kiwa.it). In any case the Organisations that intend to conclude a contract with Kiwa Cermet can request a computer copy. Kiwa Cermet will communicate all subsequent modifications to the contractual documents, but it is the responsibility of the Organisation to always have the updated version of these documents, downloading them from the website www.kiwa.it;
- Respect and enforce (for all economic subjects involved in the life cycle of the MD subject to certification), all applicable obligations, provided for by Regulation (EU) 2017/745; so by way of example and not limited to, stipulate specific contractual agreements in this sense with importers, exporters, distributors as well as stipulate and maintain in force an adequate insurance policy to cover liability pursuant to Directive 85/374/EEC to demonstrate the requirements set out in Article 10 of Regulation (EU) 2017/745. The maintenance of the insurance policy will be verified by Kiwa Cermet during the review of the certification quotation and during the audits envisaged in the certification cycle, verifying the valid Professional / Product Liability Insurance Certificate and the related receipt of payment;

- Maintaining MD conformity with the essential requirements referred to in Annex I of Regulation (EU) 2017/745;
- Provide Kiwa Cermet with all necessary information concerning the Organisation, the products or categories of products subject to the certification procedure and any critical 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 (EU) 2017/745;
- Maintain, in the technical documentation, an updated list of all the UDI-DI attributed to the MD subject to certification;
- Inform Cermet Kiwa 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 quotation 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, for certification relating to the device, which have been refused or have been withdrawn;
- Guarantee Kiwa Cermet personnel all the facilities and access to the documents necessary for carrying out the conformity assessment activities, including access, during the audit, to all areas evaluated;
- 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 Cermet with a complete and detailed report of the specific risks that exist in the workplace where Kiwa Cermet personnel will be working and the PPE necessary for carrying out the appointment, informing Kiwa Cermet personnel concerning their correct use. In this regard, the Organisation must provide the Company documentation concerning the workplace safety (D.V.R., safety plan, procedures, etc.), limited to aspects of specific interest, to the personnel appointed by Kiwa Cermet. If for such omissions, injuries occur or illnesses are contracted, no charges may be made, for any reason against Kiwa Cermet;
- Provide Kiwa Cermet with all technical, insurance and quality system documentation, both during the initial phase as well as in any other phase of the certification process;
- Provide all the documentation subject to assessment by Kiwa Cermet and the relative correspondence with Kiwa Cermet, in Italian or English. No other languages shall be accepted. For documents in English or in two languages, in the event of differences between the Italian version and the version in the other language, the Italian version shall always prevail. Documentation must be dated and signed, in uneditable format. Any modification to the content of the documents (single words/phrases, additions and removals) following any assessment by Kiwa Cermet must be identified using a methodology that allows for clear visualization in order to guarantee immediate traceability with respect to the previous revision of the document. Furthermore, a summary table of the changes shall be available. These good practices for managing changes must be formalized within the Organization's quality management system;
- Establish and implement a procedure for managing changes that impact the products subject to certification or the approved quality system, which provides for communication to Kiwa Cermet, by sending information relating to changes made and receipt of approval from Kiwa Cermet before the implementation of any modification (ref. § 4.6.1);
- Ensure the registration/information procedures provided for by the Competent Authority;
- Fulfil the obligations imposed by the quality system approved by Kiwa Cermet, 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 art of the reference sector;
- Inform the Competent Authorities and Kiwa Cermet, 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 Regulation (EU) 2017/745; moreover, in the event of a serious incident, it must carry out all activities laid down in Article 89 of Regulation (EU) 2017/745;
- For all **critical suppliers**: establish a contractual requirement with the supplier in such a way that access by Kiwa Cermet is granted to all suppliers' sites and documents (also downstream of the supply chain, where appropriate) where MD subject to certification are produced or processed, both for periodic and unannounced audits, otherwise Kiwa Cermet may refuse the certification request, or refuse to continue with it. The supplier must also provide the Organisation with all of the technical documentation and quality management system

documentation required to provide proof of conformity with the relevant safety and performance requirements and application of the quality management system;

- Maintain an updated list of codes corresponding to all devices subject to approved and signed certification, to be delivered to Kiwa Cermet in a controlled manner;
- Maintain the above obligations in case of changes to certified products, for all extensions to new products subject to certification;
- Accept, without additional costs, the potential presence of staff of the control body/competent authority as Observers, which will be notified by Kiwa Cermet with a clear illustration of their roles. Their presence has the aim of assessing that the evaluation methods used by Kiwa Cermet are in accordance with the notification requirements.

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

The Organisation must undertake to comply with the following requirements:

- Undergo appropriate conformity assessments, according to the selected Annex, before placing an MD on the market and before its commissioning.
- Plan, continuously conduct and document a clinical evaluation and a post-marketing clinical follow-up (PMCF) as provided for by Annex XIV of Regulation (EU) 2017/745 and the related guidelines and Common Specifications published by the European Commission.
- Where applicable, carry out clinical investigations according to Annex XV of Regulation (EU) 2017/745 and the related guidelines and Common Specifications published by the European Commission.
- For all MDs: prepare a technical documentation according to the chosen Conformity Annex.
- For class IIa, IIb and III MDs: draft and maintain a periodic safety update report (PSUR) as provided for in Article 86 of Regulation (EU) 2017/745.
- For class Is, Im and I-reusable surgical instruments MDs: draft and maintain a post-marketing surveillance report (PMSR) as provided for in Article 85 of Regulation (EU) 2017/745.
- For implantable and class III implantable MDs: draw up a summary of safety and clinical performance as article 32 of Regulation (EU) 2017/745.
- Agree to keep the following available for the competent Authorities and Kiwa Cermet for a period of at least ten (10) years and, and for implantable devices at least fifteen (15) years from the entry date of the last device on the market:

  a) The EU declaration of conformity drafted in accordance with the provisions of Annex IV of Regulation (EU) 2017/745;

  b) The documentation provided for in paragraph 2.1, fifth indent of Annex IX of Regulation (EU) 2017/745;

  c) The information on changes referred to in paragraph 2.4 of Annex IX of Regulation (EU) 2017/745;

  d) Kiwa Cermet's decisions and reports provided for in Annex IX of Regulation (EU) 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 Regulation (EU) 2017/745;

  g) The documentation referred to in paragraph 4.2 of Annex IX of Regulation (EU) 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.

3.3 Description and Classification of results of conformity assessment activities

The results of the documentary analysis are expressed as follows:

Critical finding: failure to comply with a requirement for certification[4] identified in the technical and/or in the quality management system documentation, relating to the MD subject to certification, which influences the ability of the product or of the related management system to achieve the expected results and therefore jeopardises the safety, the fundamental performance, the technical characteristics or the functionality of the product.

Non-critical finding: failure to comply with a requirement or partial fulfilment of a requirement for certification, which although in need of correction, does not affect the ability of the product or the related management system to achieve the expected results and therefore does not fall within the critical findings case.

The results of the audits are expressed in terms of:

Major non-conformity (NC): non-fulfilment of a requirement for certification, which affects the capability of the product or of the related quality management system to achieve the expected results, and therefore the safety, the fundamental performance, the technical specifications or the functionality of the product. It may concern:

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

Minor non-conformity (NC): non-fulfilment or partial fulfilment of a requirement for certification, which, although in need of correction, does not affect the capacity of the product or of the related quality management system, to achieve the expected results, and therefore does not imply an above-mentioned major non-conformity.

If there are more lesser not conformity, in the same requirement, according to the contents and to the general result of the audit, they can entail the issue of a major NC.

Minor non-conformity that have not be 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 Cermet 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 harmonised 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 Cermet shall operate in compliance with Regulation (EU) 2017/745, national legislative provisions[5], and 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 use Kiwa Cermet 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 Regulation (EU) 2017/745.

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

[4] Refers to a regulatory or legislative requirement, concerning the Organisation's documentation approved by Kiwa Cermet or a Kiwa Cermet contractual requirement.

[5] Italian Legislative Decree No. 137 of 5 August 2022, "*Provisions for the alignment of national legislation with the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices […]*".

In case of a disagreement between the Organisation and Kiwa Cermet regarding the application of the classification rules, Kiwa Cermet shall inform the Organisation on the matter. The Organisation and Kiwa Cermet shall be responsible for sending details relating to the points of disagreement to the Competent Authority, where the Organisation is located, which will resolve the dispute as reported in Article 51(2) of the MDR. If 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 Italy, the Competent Authority of the Organisation's Member State shall make a decision on the matter, after consulting the Italian Competent Authority.

In this case, the process cannot continue until the Competent Authority's reply is received.

4.1.3 Certification Process

The certification path followed by Kiwa Cermet for the purposes of CE marking and the maintenance thereof is represented by the provisions set out in the applicable Annexes or Articles of Regulation (EU) 2017/745, to which reference should be made.

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

For the device groups identified in Annex XVI, Kiwa Cermet will perform conformity assessments as provided for similar devices intended for medical use, and with reference to the relative Common Specifications relevance to each group in terms of risk management and clinical evaluation.

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.

4.1.4 Conformity assessment activities

The following rules apply:

- The language of the audit will be Italian or English. For other languages, the Organisation must guarantee the continuous presence of special translators to support the audit team at its own expense.
- 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 audit 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 all audit activities, the Lead Auditor issues a Report that outlines the results of the Audit.
- In the event that a Non-Conformity (NC) is reported following an audit, the Organisation must define and implement appropriate actions to resolve the NC, carry out an analysis of the causes that generated the NC and establish the consequent corrective actions required to eliminate the causes identified, with a specific procedure clearly planned in terms of the methods and implementation timelines. The Customer must notify said action plan to Kiwa Cermet within a certain period of time, as provided in the following paragraphs.
- Any difference of opinions between the Audit Team and the Organisation, concerning the results of the Audit or its conclusions, must be discussed and resolved, wherever possible. In the event of any non-resolved differences of opinion, the Organisation can express its reservations on the results of the Audit.
- 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 Cermet reserves the right to further examine the aspect reported.
- All conformity assessments reports and the results of 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 745, informing the Organisation.

4.1.5 Specific additional procedures

For some types of MDs, 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 Cermet shall evaluate the consequent actions to be taken including specific limitations or conditions (see § 4.10).

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 active Class IIb devices intended to administer a medicinal product to, or to extract a medicinal product from, the human body, as per Annex VII point 6.4 (rule 12) of the MDR, Kiwa Cermet conducts an assessment of the clinical data reported in the clinical evaluation report prepared by the Organization and produces an assessment report that is transmitted to the European Commission to initiate the Clinical Evaluation Consultation Procedure (CECP). The Commission, in turn, transmits it to the Expert Panel referred to in Article 106 of the MDR. Except in cases where such consultation is not deemed necessary according to Article 54.2 of the MDR, Kiwa Cermet cannot proceed with the certification process until the Expert Panel provides a scientific opinion on the relevance of the clinical data and the Kiwa Cermet assessment report, in particular regarding the determination of the benefit-risk ratio, the consistency of such evidence with the medical indications and the PMCF plan. Only if, after 60 days from the submission of the documentation to the Expert Panel, no opinion is received, Kiwa Cermet will proceed with the certification activities.

b) For devices that incorporate a substance which, if used separately, could be considered a medicinal product according to Article 1, point 2 of Directive 2001/83/EC and which has an accessory action to that of the device, Kiwa Cermet will assess the Organization's documentation to verify the quality, safety and usefulness of the substance contained in the MD in analogy to the methods of Annex I of Directive 2001/82/CE, as well as the benefits and risks deriving from the inclusion of the substance in the device; the results of the analysis will be reported by Kiwa Cermet on specific forms of the Competent authority and sent to the latter, which will be selected, in agreement with the Organization, among those designated by the European Member States in accordance with Directive 2001/83/CE. Kiwa Cermet cannot proceed with the certification process until the Competent Authority has issued a favorable opinion. In case of a negative opinion, it will not be possible to issue the certification.

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 745 Article 52, paragraph 11), Kiwa Cermet shall carry out the analysis of the Organisation’s documentation regarding the conformity 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.

d) For devices manufactured using cells or tissues of animal origin rendered non-viable, or with products rendered non-viable derived from animal tissues (pursuant to Regulation 745 Article 52, paragraph 10) the Organisation must apply the additional provisions set out in Regulation (EU) 722/2012. Moreover, before proceeding with the conclusion of the certification process Kiwa Cermet must send the results of the document evaluation to the competent authorities and act on any comments received.

4.2 Activation of the certification process

4.2.1 Requests for certification

In order to access certification services for medical devices (first certification, for extensions, or in the re-certification phase), the Organisation must complete the informational questionnaire (MOD PO 09 MED-MDR) prepared by Kiwa Cermet, which is sent upon request.

For class III and IIb MDs, Kiwa Cermet shall only accept the certification procedures referred to in Annex IX.

If the Organisation chooses the conformity assessment process according to Annex IX, for class III and class IIb MDs referred to in Article 52 § 4, must also submit a specific request for conformity assessment of the technical documentation provided for in Chapter II of Annex IX. This request must contain a description of the design, manufacture and performance of the MD.

Together with the duly completed informational questionnaire, the Organisation must also send Kiwa Cermet the annexes required in particular the following:

- 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 or its crucial suppliers.

4.2.2 Preparation of the quotation

Based on the analysis of the information reported in the questionnaire MOD PO 09 MED-MDR, Kiwa Cermet prepares the financial quotation for CE marking certification, containing the description of the service offered and all information relating to the activities, and the prices determined in accordance with the rates in force.

In the event that aspects were to emerge from the information contained in the questionnaire due to which Kiwa Cermet cannot guarantee the ability to perform the certification activity, Kiwa Cermet communicates to the Organisation the impossibility to issue the quotation, with the related reasons.

4.2.3 Acceptance of the quotation

Signing the quotation by the Organization's Legal Representative[6] (or by a legally empowered person) constitutes the official application, as intended in Annex VII, point 4.3 of the MDR, and also establishes the contractual relationship between the parties for the conformity assessment activity for the purpose of CE marking.

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

Acceptance of the quotation entails the sending by the Organisation of all the documentation referred to in the Annex chosen for the assessment and of the valid Professional/Product Liability Insurance Certificate produced, with the relative receipt of payment.

If inconsistencies emerge in the subsequent document assessment phase or during the audit with regard to statements made in the informational questionnaire, the quotation may be subject to review by Kiwa Cermet.

4.2.4 Review of the application and order confirmation

Once Kiwa Cermet has received by theOrganisation the signed quotation and all of the documents requested therein and in the informational questionnaire, Kiwa Cermet will review said documentation, ensuring that:

- The data and documents required have been provided in a comprehensive manner;
- Both parties have clearly defined and understood the certification service requirements;
- Kiwa Cermet is able to carry out the required activities (including the availability of sufficient and adequate resources);
- There are no differences compared with the data provided at the time of the quotation request.

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

In the event of a negative outcome, Kiwa Cermet is entitled to request all the additions or amendments necessary before starting the procedure or to communicate the impossibility of such start-up, justifying the reasons for the Organisation. If the outcome is negative due to technical reasons connected to product safety, Kiwa Cermet shall be in a position to refuse the application for certification, providing the Organisation with the relative reasons and uploading the refusal to the Eudamed system.

Should the Organization request the withdrawal of the certification application (either in full or for specific devices), it must provide written notification signed by its Legal Representative (or a legally delegated person) to Kiwa Cermet. Kiwa Cermet may accept such withdrawal – through a separate written communication to the Organization – only if no deficiency has been identified by Kiwa Cermet (as a result of the conformity assessment activities) that could lead Kiwa Cermet to reject the certification application.

In the event that Kiwa Cermet accepts the withdrawal of the certification application, the withdrawal of the application shall be equivalent to the Customer's termination of the certification contract with Kiwa Cermet limited to the MDs to which the withdrawal of the application refers (consequently, the Customer shall comply with the provisions of Article 11).

4.2.5 Planning of the conformity assessment activities

Conformity assessment activities are identified on the basis of the chosen conformity assessment procedure. In general, they involve:

1. A documentation analysis;
2. Planned audits at the site/s of the Organisation (as described below) and critical suppliers (if applicable);
3. An unannounced audit;
4. Product testing activities.

[6] Intended as *Manufacturer* as defined in Article 2 (30) or the natural or legal person referred to in Article 22 paragraph 3.

Depending on the type of request made by the Organisation (such as new certification, extension, change), Kiwa Cermet determines which compliance assessments are to be carried out (described in the quotation) and defines the human resources to be involved.

The activities can be assigned to employees or qualified external collaborators according to the requirements of Kiwa Cermet procedures.

If a situation arises that requires subcontracting of part of the certification process, Kiwa Cermet shall implement all measures necessary to ensure that the subcontractor complies with the provisions of reference and with the relevant Kiwa Cermet regulations. Liability for any subcontracted activities remains that of Kiwa Cermet.

4.3 Initial analysis of the documentation

Documental analysis serves the purpose of checking compliance of the documents relating to the product to be certified with the applicable Requirements of Regulation 745.

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

The technical documentation must include at least the elements reported in Annexes II and III of Regulation (EU) 2017/745 and will be prepared by the Customer according to the Position Paper of the European Notified Bodies association Team-NB "*Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of Medical Device Regulation (EU) 2017/745*" (available on the website https://www.team-nb.org/team-nb-documents/).

The quality system documentation must include at least the contents of Annex IX point 2, and Annex XI part A POINT 6 of the MDR.

Kiwa Cermet intends the assessment of conformity with Requirements as a test to verify the solutions adopted by the Organisation to meet minimum requirements throughout the life-cycle of MD subject to certification, including the transport, installation, use and decommissioning phases, to ensure the safety and performance claimed in its intended purpose. Particular attention will be paid to the solutions adopted in the design, manufacturing, packaging, labelling and use phases, verifying that all the risk management conditions have been met, including those provided for by the ISO 14971 standard and verifying that the safety principles have been applied in a compatible way based on the current level of knowledge and state of the art.

Documents and test reports pertaining to the pre-clinical and clinical data shall also be verified. The results of tests performed by the Organisation and included in the technical documents, 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 (such as IECEE CB, university centers of excellence). The use of other laboratories or Manufacturer's internal 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 Cermet 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 Cermet, 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 categories of products. This shall not apply to implantable class III and IIb devices[7], 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 Cermet and make it available on request at any time and during the assessment activities and for the entire period of validity of the assessment contract with Kiwa Cermet.

At the end of the initial documentary analysis, the relative reports are issued summarising the outcome, with any remarks. Depending on the result of the analysis of documentation, the Organisation will be able to decide if to

[7] 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.

integrate or modify the documentation based on the findings or terminate the certification process. When the Organisation sends the correct documentation, a further evaluation is carried out.

The correct or integrated technical documentation must be sent in complete form.

In the event of any findings, the Organisation must send to Kiwa Cermet, on the specific form received, within 20 working days from the date of receipt of the report, the proposal for resolution of the findings, with the relative implementation timelines.

In the case of critical findings, it will not be possible to plan and carry out the initial certification audit if the critical findings relating to the documentation have not been resolved and closed (with a specific additional assessment).

In the case of non-critical findings, it will be possible to proceed with the certification process, planning and carrying out the certification audit. Verification of the closure of these findings will be carried out with a specific and additional assessment.

The positive completion of the phase of the documentation analysis must, in any case end within 1 year from the date of the first analysis of documentation; beyond said limit, Kiwa Cermet will assess the subsequent actions, including a complete re-assessment of the documents or the interruption of the certification process. In this last case, the application will be refused, with consequent loading of the refusal on the Eudamed system. These decisions may also be taken as a function of significant changes to the regulatory or normative context of reference relative to the state of knowledge of the product subject to certification, or of any changes relating to the Organisation's processes or sites. If there are significant changes, the maximum time of 1 year may be reduced at the discretion of Kiwa Cermet.

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.

During the certification audit, the assessment of all the characteristics of the device, at a documentary and application level and the evaluation of the quality system applied to the product will be carried out.

The certification audit is planned in order to take all the applicable requirements of Regulation (EU) 2017/745 into consideration and has to be carried out within a maximum of 6 months from when the successful completion of the documentation analysis.

Beyond this limit, Kiwa Cermet will evaluate the consequent actions, including for example restarting with a new certification process or interrupting the certification process; in the latter case the application will be refused, with consequent loading of the refusal on the Eudamed system. These decisions may also be taken as a function of significant changes to the regulatory or normative context of reference, or to any technological developments relative to the state of knowledge of the product subject to certification, or of any changes relating to the Organisation’s processes or sites. If there are significant changes, the maximum time of 6 months may be reduced at the discretion of Kiwa Cermet.

In defining the aspects to be verified, Kiwa Cermet decides on the crucial suppliers that will be audited. Kiwa Cermet may decide, also based on the results of periodic audits, not to carry out the audit at a critical supplier if:

1. the supplier is certified by Kiwa Cermet with reference to the schemes: ISO 13485, MDR in Annex IX or XI or ISO 9001, for the processes/services it provides to the manufacturer (related to the MD to be certified);
2. the supplier is certified by another Accredited or Notified Certification Body for similar schemes referred to in the previous point and is adequately monitored by the client Organisation[8];

provided that there are no other elements that cast doubt on the ability of the critical supplier to provide the Organisation with products/services that comply with the required specifications.

The Lead Auditor prepares an activity plan that is sent to the Organisation. Any changes to the plan can be agreed upon on the basis of Organisation requirements during the initial meeting during the audit.

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

During the certification audit, the Lead Auditor shall also prepare the periodic conformity assessments programme. This programme forms the basis for subsequent detailed planning of each individual audit.

[8] In the case of test laboratories or calibration centres, the ISO 17025 accreditation issued by a recognised Accreditation Body or the authorisation according to Good Laboratory Practices, or laboratories that are internationally recognised test centres are also considered valid.

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 following the audit, 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 Cermet via the appropriate form within 20 working days from the date of the audit.

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

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

For major NCs, the certificate cannot be issued until the implementation of changes and corrective actions has been verified through an additional conformity assessment according to the assessment procedures established by the Lead Auditor (audit at the Organisation's premises and/or by means of documentary analysis, where possible). Said assessment must be carried out within 6 months from the audit certification; beyond said limit, Kiwa Cermet will decide at its own discretion whether to assess subsequent actions.

The implementation and effectiveness of changes and corrective actions referring to Minor NCs is monitored by Kiwa Cermet during the following planned Surveillance Audit. Based on the number and nature of the minor NCs found, Kiwa Cermet will be able to allocate additional time for the closure of these findings (the related costs are borne by the Organisation).

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

The approval of the certificate is conducted by personnel with technical and clinical *expertise*. Such personnel can not in any way have taken part in the conformity assessment activities. During the certificate approval process, personnel involved in the approval process 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 § 4.9 and 4.10).

Each different assessment with respect to what has been reported by the Audit Team shall be communicated to the customer.

If the approval process is positive, Kiwa Cermet issues a declaration of conformity that is sent to the Organisation.

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

Once it has received certification, the Organisation applies the notification number 0476 (identification number of Kiwa Cermet) on certified devices.

If certification is refused, Kiwa Cermet 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 of certification can also occur as a result of negative opinions expressed by other competent Authorities, consulted as required by Regulation 2017/745. The refusal shall be uploaded to the Eudamed system.

4.5 Surveillance Audit

The performance of surveillance audit activities during the certification cycle is subject to the regular payment of invoices for previous activities by the Organisation. Conversely, Kiwa Cermet reserves the right not to carry out the planned activities and proceed with certificate suspension or withdrawal.

4.5.1 Scheduled Surveillance Audits

Scheduled surveillance audits are carried out once every 12 months from the previous surveillance audit, bearing in mind that the first surveillance audit must be carried out at the latest within 12 months from the certification granting date. They are always carried out at the sites where activities related to products subject to certification take place.

The purpose of the scheduled surveillance audit is to ensure that the Organisation applies the approved quality management system and the post-marketing surveillance plan[9], verifies the maintenance of the conditions that led

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

to the granting of certification, as well as any changes to the process or products, if requested in advance (see § 4.6.1) and approved by Kiwa Cermet.

Before the surveillance audit Kiwa Cermet will request the following updated documents: technical dossiers, updated quality system documents, evaluation reports of clinical data including post-marketing surveillance and post-marketing clinical follow up data, PSUR and PMSR and where applicable the summary in accordance with Article 32 of the 2017/745 Regulation. This documentation must be provided at least 30 days before the date of the audit.

It shall be the responsibility of the Organisation to send the correct and updated documentation to Kiwa Cermet, 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 crucial suppliers as defined in the periodic 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 Cermet can perform sampling and laboratory tests on the certified medical device (see § 4.5.3). For class III MDs, tests will always be carried out on the parts and/or the approved materials, essential for the integrity of the MD, including, where appropriate a check that the quantities of parts and/or materials produced or purchased correspond to the quantities present in the finished MDs.

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

At the end of the audit, Kiwa Cermet Audit Team gives a copy of the audit report to the Organisation, who signs it. The report can be considered confirmed if within 60 calendar days no further notification is given to the Organisation.

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 Kiwa Cermet Lead Auditor via the appropriate form within 20 working days.

The Lead Auditor shall assess the actions proposed; if accepted, they will be communicated to the Organisation within 15 calendar days.

The implementation and effectiveness of changes and corrective actions referring to Minor NCs is monitored by Kiwa Cermet during the following scheduled periodic Surveillance Audit. Based on the number and nature of the minor NCs found, Kiwa Cermet will be able to allocate additional time for the closure of these findings (the related costs are borne by the Organisation).

For every Major NC, the implementation of corrections and corrective actions shall be evaluated with a supplementary assessment, in accordance with the methods established by the Lead Auditor (audit at the Organisation's premises and/or by means of documentary evidence, where possible). This assessment must be carried out within the timelines set out by Kiwa Cermet and in any case no later than 6 months from the surveillance audit; beyond the established timelines, Kiwa Cermet will evaluate the consequent actions at its discretion. If the abovementioned assessment is positive, certification is confirmed. If the Organisation fails to implement the agreed upon actions for the approval of irregularities within the granted terms, 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).

4.5.2 Document analysis for surveillance

In order to maintain the certification, Kiwa Cermet must carry out, on an annual basis, a verification of the maintenance of the conformity of the documentation relating to the certified products.

The verification of the technical documentation will normally take place concurrently with the scheduled surveillance audits and may take place on-site or off-site, based on the scheduling needs of the activities.

If possible, the verification of the documents relating to clinical data will be organised close to or concurrently with the scheduled surveillance audit, but will not normally be carried out at the Organisation's premises.

For class III devices and implantable devices, Kiwa Cermet must also verify the periodic safety update report (PSUR), through the Eudamed system, according to the frequencies set out by Regulation 745; it is the responsibility of the Organisation to upload this report to Eudamed according to the timing provided for by Regulation 745 based on the class of the device being certified.

In the event of any findings, the Organisation must send to Kiwa Cermet, on the specific form received, within 20 working days from the date of receipt of the report, the proposal for resolution of the findings, with the relative implementation timelines. Moreover, it will be necessary to carry out an additional assessment to verify their resolution, which will have to take place:

- in case of critical findings: within 3 months of receipt of the findings by the Organisation,
- in case of non-critical findings: within one year of receipt of the findings by the Organisation, but in any case before the subsequent annual surveillance documentary analysis.

Kiwa Cermet will be able to define different timeframes according to the nature of the findings and the actions necessary for their resolution.

4.5.2 Unannounced Surveillance Audit

Kiwa Cermet performs unannounced audits at least once every 5 years, at sites where activities related to the products subject to certification are carried out (these must also include local crucial suppliers), in order to verify the daily compliance of the requirements by the Organisation.

Kiwa Cermet can increase the frequency of audits without notice, such as in cases where the devices have a high potential of risk and/or are often non-compliant and/or specific reasons exist to suspect the non-conformity of the devices and/or the Organisation.

In order to ensure the proper performance of unannounced audits, the Organisation agrees to provide Kiwa Cermet with information on the periods of the year during which the manufacture of the medical devices subject to certification does not take place (company closures, holidays, production stoppages, etc.).

In addition, in agreements governing the relationship with its critical suppliers, the Organisation agrees to include prior authorisation for Kiwa Cermet 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 Organisation, which in turn shall promptly inform Kiwa Cermet, with information on the periods of the year in which they do not carry out their activities on behalf of the Organisation (company closures, holidays, production stops, etc.).

Kiwa Cermet Audit Team arrives at the sites where activities related to the products subject to certification are conducted, identifying themselves by identification badges and letters of identification. The Organisation can contact Kiwa Cermet's offices and request confirmation of the activities.

When carrying out unannounced audits, Kiwa Cermet performs checks on an appropriate sample of newly-manufactured medical devices, preferably taken from the manufacturing process in progress at the time of the audit, in order to ascertain conformity with the technical documentation and to the provisions of the law, also by means of tests. If a difference between the sample taken from the manufactured devices and the specifications mentioned in the technical documentation is found, Kiwa Cermet suspends or withdraws the relevant certificate or imposes specific reductions/limitations (as applicable).

In case the Organisation (or its critical suppliers), refuse to receive an unannounced audit, it must formalise this refusal (on letterhead paper with stamp and signature) and quotation the reasons for which it has not been possible to carry out with the audit. Kiwa Cermet shall reserve the right to assess the subsequent actions, which may lead to the suspension or withdrawal of certification. The Organisation is informed promptly in relation to the 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 Cermet shall be entitled to terminate the agreement and withdraw the certification.

In case of availability of Kiwa Cermet auditors and of availability of the Organisation, the unannounced audit can be combined with the regular surveillance audit.

At the end of the unannounced audit, the Lead Auditor gives a copy of the audit report to the Organisation and files a copy of the records of the tests carried out on the day of the audit and compiled by the Organisation's and/or critical supplier's officer who was in charge of carrying out the tests.

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 Organisation 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 announced audit occurs according to the same method described in § 4.5.1.

4.5.3 Product testing activities

As well as during unannounced audits, Kiwa Cermet can also carry out product tests in any surveillance audit, based on the class of the device, or at any time of the certification cycle, based for example on reports, complaints, cases of suspected non-conformity of the product etc.

The tests can be carried out by taking a sample from the Organisation or even following the withdrawal of certified devices from the market. The tests mentioned can be performed:

- at the site of the Organisation or crucial Supplier, directly by the personnel responsible and under the supervision of the Audit Team, who shall also investigate the use of competent personnel, suitable environments and measurement tools calibrated by accredited calibration centres and therefore with a metrological traceability guarantee.
- at Kiwa Cermet Laboratory or with external laboratories qualified by Kiwa Cermet. In special cases, when the tests comprise protocols not easily performed by laboratories, laboratories recommended by the Organisation can be chosen, provided that the test is performed under the supervision of a Kiwa Cermet expert.

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.

4.6 Changes or Extensions

4.6.1 Changes

The Organization shall inform Kiwa Cermet in advance of any plan for changes it intends to undertake, in relation to the following:

- changes to the approved [10]quality management system or to the range/type of certified products;
- changes to the approved design[11] and to the software, of the device;
- changes to the intended purpose, to the conditions of use and to the claims attributed to the device;
- changes to the approved type of 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 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.

The modification request must be submitted to Kiwa Cermet in writing, in the form of a report containing at least the following information:

- a clear description and identification of the requested change, with a comparison to the approved situation (including pictures, if applicable) and supporting documents;
- device to which the change refers (e.g., codes, model, etc.);
- reference technical file and its impact;
- reference MDR certificate number;
- rationale to define the modification as *substantial*[12] or *non-substantial* in accordance with NBOG 2014-3.

[10] 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.
[11] Including materials, packaging, safety and performance requirements.

On the basis of the information and documents received, Kiwa Cermet shall assess each communicated modification project 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 Organisation in writing.

In the event of modifications classified as substantial, such modifications may only be implemented following a specific preliminary evaluation and approval process by Kiwa Cermet. Therefore, the Customer must submit an official modification request in accordance with the procedures described in the preceding § 4.2.1, namely by completing the information questionnaire, which will be followed by a quotation containing the necessary evaluation activities. This quotation constitutes the formal request for the modification and is also an integral part of the existing contract between Kiwa Cermet and the Manufacturer.

In the event of a modification classified as non-substantial, the Customer may implement the modification after receiving the official communication from Kiwa Cermet, containing the terms for verifying the application of such modification during subsequent evaluation activities provided for by the ongoing certification process.

It shall not be possible to process requests for changes that have not previously been communicated, during periodic documentary evaluations or during periodic audits at the Organisation's premises. Furthermore, it will not be possible to process modification projects related to the same technical documentation, requested from Kiwa Cermet at different times and therefore pertaining to different formal modification requests. In such cases, Kiwa Cermet will proceed sequentially with the evaluation activities provided for in each individual formal modification request.

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

4.6.2 Extensions

Any addition to the contents of the certificate, relating to products or sites., shall be considered an extension of the certification.

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

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

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

4.7 Re-certification and renewal of the certificate

The re-certification follows the same rules as the initial certification (including the analysis of the documentation).

The Manufacturer is required to apply for certification renewal no later than 12 months prior to the certificate's expiration date.

At least 9 months before the expiry of the certificate, Kiwa Cermet must perform a documentary evaluation for the renewal of the certificate, which aims to enable an effective review of the conformity of the quality management system and of the products subject to certification.

Before the re-certification audit Kiwa Cermet shall request the following updated documents: technical documentation, quality system 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 in accordance with Article 32 of Regulation 2017/745.

During the re-certification, the performance of the management system in the previous certification cycle shall also be reviewed.

During the re-certification, the Organisation is required to submit a summary of the changes and of the scientific results related to the device being certified, including, at a minimum:

[12] Any change that could affect the safety, performance, conditions of use of the MD and/or the conformity of the quality management system related to the MD with respect to the applicable requirements of the MDR, including the requirements of Annex I.
For further details on substantial and non-substantial changes, please refer to document NBOG 2014-3 "*Guidance for manufacturers and notified bodies on reporting of design and changes of the quality system*".

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 conformity with the general safety and performance requirements set out in Annex I of Regulation 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 or clinical investigations of similar devices,
- data from registers and registries,
- resulting experience related to similar devices.

The management of the results of the documentary analysis and of the re-certification audit takes place according to the same procedures described in paragraphs 4.3 and 4.4. In case of Major NCs, it will not be possible to proceed with the renewal of the certification before the verification of the closure of the major NC.

If it is not possible to verify the closure of the Major NC by the expiry of the certificate, the renewal must in any case take place within the following 6 months; however, until the certificate is renewed the products will no longer be able to carry the reference to the certification and can no longer be placed on the market with the CE marking nr. 0476.

Beyond the 6-month timeframe, if the renewal has not been completed, Kiwa Cermet shall have to refuse the renewal request, 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.

The execution of re-certification activities is subject to the regular payment of the aforementioned activities by the Organisation. Otherwise, Kiwa Cermet reserves the right not to perform the activities planned for the renewal of the certificate and to proceed with the refusal of the renewal application as indicated above.

4.8 Other conformity assessment procedures

Importers and distributors who carry out the activities referred to in Article 16 point 2 of Regulation 745, must submit an application to Kiwa Cermet for certification of the quality management system as required by § 4.2.

Kiwa Cermet shall directly carry out the certification audit and the consequent activities, as provided for in § 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 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 conformity 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 maintenance and renewal of the certification shall follow the specifications set out in § 4.5 and § 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 Cermet 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, given the impossibility for the Organisation to refuse the members of the Audit Team commissioned by Kiwa Cermet, maximum attention shall be given to their selection.

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.

The additional assessments shall be charged to the Organisation, they shall not replace or modify the procedure and frequencies associated with periodic surveillance assessments and shall be communicated in advance to the Organisation.

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

4.10 Specific conditions

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

These limitations or 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, to the intended purpose of a device for certain groups of patients, different frequencies of conformity assessments (e.g. for the evaluation of clinical data), specific post-marketing clinical follow-up studies in accordance with Annex XIV, part B of Regulation 745.

5. CHANGE OF NOTIFIED BODY

The change of Notified Body takes place only in the event of a voluntary change on the part of the Organisation.

The voluntary change of the Notified Body is managed by Kiwa Cermet in compliance with the provisions of Article 58 of Regulation (EU) 2017/745. In particular, Kiwa Cermet will ask the Organisation (or its authorised representative) to sign an *Agreement* that details the provisions of the aforementioned Article.

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

The procedures for transferring the certification from the outgoing Body to Kiwa Cermet may include a complete conformity assessment process (as described in § 4) or a partial assessment process. These methods will be established by Kiwa Cermet according to various aspects including: reasons for the change of NB, criticality and number of products etc. and are always agreed upon with the Organisation in the quotation phase.

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

In addition to the documentation requested in § 4, upon receipt of the accepted quotation, Kiwa Cermet also requests the following additional documents:

1. A copy of the complete audit reports for the first certification (or the last re-certification and the last surveillance audit report, conducted by the former/outgoing Notified Body.
2. A copy of the complete document assessment reports for the first certification (or the last re-certification) and the last surveillance, including evaluations of clinical and post-marketing data (including the PSUR, PMCF, PSR and SSCP), for all certified products.
3. Any documentation outlining the management (treatment, corrective actions) of NCs identified;

4. Complaints received, data on supervision and evidence of their management;
5. Audit programme and sampling plan of the outgoing Body;
6. A copy of EU certificates issued by the outgoing Body;
7. A copy of quality system certificates or EU certificates (if any) for critical suppliers;
8. Communication to Kiwa Cermet of residual lots marked with the number of the outgoing Body;
9. *Labelling* of products certified by the outgoing Body and drafts of the new labelling;
10. Declaration of conformity of certified products by the outgoing Body and drafts of the new declaration.

For the purpose of the voluntary change of NB, the certificates to be replaced must be valid.

The certification transfer activity (issuing the certificate) can only be completed when Kiwa Cermet is certain that the previous EU certificate has been revoked, through notification from the outgoing NB regarding the revocation of the existing EU certificate.

6. ACTIVITIES RESULTING FROM THE CHANGES TO THE DESIGNATION OF OTHER NOTIFIED BODIES

Based on the provisions of Article 46 of the 2017/745 Regulation, 3 situations can be identified:

1. **cessation of the activity** of an NB.
2. **limitation or suspension** of the designation of an NB;
3. **withdrawal** of the designation of an NB.

If Kiwa Cermet receives and accepts an application for certification for products certified by NBs subject to cases 1 and 3, the activity will be managed as a new certification and the procedure indicated in the previous paragraphs will then follow.

If Kiwa Cermet receives and accepts an application for temporary assumption of the functions of the NB, with reference to the certificates issued by an NB subject to the provisions referred to in point 2 above, Kiwa Cermet does not issue any certificate, but temporarily takes over the surveillance and monitoring activities of the certificates issued by the other NB, assuming the relative responsibilities. In this situation, the instructions provided by the responsible Competent Authority will be followed.

The applications relating to cases 2 and 3 will be acceptable only if the responsible Competent Authority has also formally confirmed that the certificates have not been unduly issued and there are no problems in terms of the safety of the MDs.

If Kiwa Cermet decides to accept the certification application referred to in cases 1 or 3, it will assume responsibility for the EU certification:

- immediately in case of withdrawal of the designation of the previous Body, but the evaluation process must be completed within 12 months from the revocation of the designation;
- to complete the full assessment of the devices, in the event of cessation of the activity of the outgoing NB, which must take place within 9 months of the cessation of the activity of the outgoing NB.

In the event of cessation of the outgoing NB's activities, it is necessary to receive from the customer a communication from the outgoing NB of the termination of the contract, with exact indication of the date of cessation of activity.

In case of limitation, suspension or withdrawal of the designation of the other NB, the customer must receive a communication of termination of the contract with the other NB or a communication from the competent Authority.

7. SUSPENSION, WITHDRAWAL OR REDUCTION OF THE CERTIFICATION

The certification can be suspended, withdrawn or reduced for the reasons already indicated in these Regulations, 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 Cermet 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 Cermet in advance and approval by Kiwa Cermet;
- References to certification or use of Kiwa Cermet 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 Cermet 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 Cermet reserves the right to:

- Request the Organisation to recall the products already placed on the market;
- For suspension cases: allow the Organisation to continue marketing the products already manufactured and issued at the date of the suspension for a period of 6 months from the date of suspension, upon receipt by the Organisation of a communication signed by the Legal Representative, specifying the lots of products concerned in stock. In this case, Kiwa Cermet reserves the right to conduct an audit at the Organisation's premises before providing approval for the products to be placed on the market. Said audit shall be charged to the Organisation.
- For revocation 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. 0476 can no longer be sold.

During the suspension period, the Organisation loses the right to refer to the certification and use the CE 0476 marking and relative certificate and must stop using all advertising material that contains relative references and return any certification documents to Kiwa Cermet upon request.

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

Except in exceptional cases (approved by Kiwa Cermet 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 Cermet 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 Article 1456 of the Italian Civil Code of the agreement to which this Regulation applies, except, in any case, the compensation of any damages suffered by Kiwa Cermet.

Following certification withdrawal, the Organisation loses the right to refer to the certification and use the CE 0476 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 Cermet to the Competent Authority using the Eudamed system, with information concerning the reasons and medical devices to which it applies.

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

8. USE OF CERTIFICATION, 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 Cermet.

If incorrect use of the certification, certificate or CE marking is found, Kiwa Cermet withdraws the certification and notifies the Competent Authority. In severe cases (such as unlawful marking, fraudulent use) Kiwa Cermet shall also provide notice to the Italian Public Prosecutor.

9. COMPLAINTS, APPEALS AND DISPUTES

9.1 Complaints

The Organisation may present documented complaints regarding its dealings with the certification activities provided by Kiwa Cermet.

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 Cermet conformity assessments.

Complaints must be sent in written form (any type of support is accepted) and must describe the situation for which the complaint is made in detail.

Kiwa Cermet records all complaints, examines them, and informs the claimant of the actions taken within thirty days of receiving the complaint.

Kiwa Cermet 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 www.kiwa.it website

9.2 Appeals

If the claimant is not satisfied with the response received, or intends to appeal against the decision of Kiwa Cermet, he 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 Cermet, it must be presented to Kiwa Cermet within 10 calendar days of the decision being communicated.

Kiwa Cermet will give the petitioner a written reply and will give notification of any actions to be taken within 30 days of the date of receiving the appeal.

A detailed description of how to lodge complaints is available on the www.kiwa.it website

9.3 Disputes

Any dispute between the Organisation and Kiwa Cermet shall be managed in compliance with Article 18 paragraph 1 of the *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders.*

10. UNILATERAL MODIFICATION OF THE CONTRACT

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

Should the Organisation not intend to accept the changes, it may withdraw from the contract by giving written notice by registered letter with return receipt or certified mail within 30 calendar days, under penalty of forfeiture, from the day following the communication to Kiwa Cermet.

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

11. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT

Kiwa Cermet may freely withdraw from the Agreement with the Customer Organisation by giving written communication to the Organisation with a notice of six months from the effective date of withdrawal. The withdrawal by Kiwa Cermet determines the withdrawal of the issued certification. The Organisation is in any case obliged to pay Kiwa Cermet 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.*

In particular, for notice of less than three months and more than two weeks from the scheduled Audit, the Organisation must pay 50% of the amount relative to the cost foreseen for the subsequent activity as agreed upon in the Agreement. For periods of notice of less than two weeks, the conditions specified in the *General Terms and Conditions* shall apply.

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