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Rev.	Revision summary	Date
2	Introduction of details on appropriate surveillance transfer, other changes to withdrawal.	2024-01-22
1	Graphic changes, corrections of misprints and improved references to CAP_Corrective Action Plan and to significant changes.	2023-09-21

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1. SCOPE AND FIELD OF APPLICATION

This regulation defines rights and obligations, terms and conditions as well as the operational methodology that govern the relationships between Kiwa Cermet Italia S.p.A. (hereinafter referred to as "Kiwa Cermet") and the manufacturer or authorised representative (hereinafter referred to as "Customer" or "Organisation") to provide the service of the appropriate surveillance on MDs (hereinafter referred to), pursuant to Article 120 (3 e) of Regulation (EU) 2017/745 and subsequent amendments[1] (hereinafter referred to as "Regulation" or "MDR").

Medical devices, manufacturer and authorised representative are defined in Article 1, paragraph 2 of Directive 93/42/EEC and subsequent amendments (hereinafter referred to as "Directive" or "MDD").

This regulation applies to medical devices which are considered Legacy Devices[2] and their accessories (hereinafter collectively referred to as "MDs" or "Devices"). In particular, MDs:

I. have a certificate issued by a notified body (hereinafter referred to as "Notified Body" or "NB") pursuant to the Directive and valid in accordance with Article 120 (2) of the MDR; and

II. are subject to the appropriate surveillance in compliance with the provisions of Article 120 (3 e) of the MDR.

According to recently changed standards MDs complying with the requirements under Article 120 of the MDR may benefit from the extension to the MDR transitional period pursuant to Article 120 (3 a) of the MDR, during which such MDs can be placed on the market or put into service (hereinafter referred to as "Transitional Period").

Conformity assessment activities referred to in the appropriate surveillance include the activities described in paragraphs 4.2 to 4.5 and are performed on MDs:

a) by reason of and pursuant to the agreement entered into with the Customer, which comprises: (i) the quotation accepted by the Customer; (ii) this regulation[3]; (iii) *Kiwa Regulation for Certification;* (iv) *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders* (the document mentioned in point (iv) is hereinafter referred to as *"General Terms and Conditions")*; and

b) pursuant to Article 120 of the MDR, Articles 11 and 12 of the MDD and in accordance with European applicable directives and guidelines as well as sector standards in their harmonised versions at the time of the performance of the activities, for such documents set out provisions which are additional to the aforesaid MDD and MDR.

The requirements provided for in this regulation constitute an integral part of the agreement entered into with Kiwa Cermet. Such requirements only refer to aspects specifically connected with the scope of the requested certification.

If any inconsistency occurs between the Italian and the English version of any documents relevant to the certification process, the Italian version shall prevail.

In interpreting this regulation the following definitions refer to any third party providing a product or a service in connection with the MD subject to certification:

- "Supplier": organisation or legal person external to the Customer providing a product or a service in connection with the MD subject to certification which does not affect the safety and performance of such MD;
- "Critical Supplier": organisation or legal person external to the Customer providing materials, components or services which significantly affect the design and production process of the MD subject to certification with regard to safety and performance (e.g. design, components on specifications, special processes, critical raw materials, critical semifinished products, etc.). Subsuppliers in downstream supply chains are also included among such suppliers, if they are regarded as critical with regard to what stated above.

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, on medical devices, […] repealing Council Directives 90/385/EEC and 93/42/EEC, amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 as regards the dates of application of certain of its provisions and subsequently by Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 as regards the transitional provisions for certain medical devices [...].

[2] "Legacy Devices" shall mean devices which are covered by a certificate issued by a NB pursuant to Directive and can be placed on the market after the date of application of the MDR (i.e. May 26, 2021), in accordance with the provisions referred to in Article 120 of the MDR. Such devices can be: class I devices pursuant to Directive 93/42/EEC (MDD), for which a CE declaration of conformity was drawn up before May 26, 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a NB; devices covered by a valid CE certificate issued under the MDD before May 26, 2021.

[3] As to the existing agreements of the conformity assessment of MDs between Kiwa Cermet and the Customer, this updated version of the *REGULATION FOR CE CERTIFICATIONS PURSUANT TO MEDICAL DEVICES DIRECTIVE – RG 01 MED_MDD* entirely and legally replaces and supersedes the previous version.

Product types on which Kiwa Cermet is authorised to work are listed in the notification of authorisation issued to Kiwa Cermet by the Designating Authority[4].

The agreement expressly excludes any form of consultancy to the Customer that may jeopardise the independence of assessments.

This regulation is also available on Kiwa Cermet website (www.kiwa.it). Customers who desire to enter into an agreement with Kiwa Cermet may request an electronic copy.

Kiwa Cermet shall also inform the Customer of all subsequent amendments to contractual documents; the Customer is responsible for having the latest version of such documents by downloading them from the website www.kiwa.it

2. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER

Kiwa Cermet applies the following principles and the *General Terms and Conditions* to perform the conformity assessment:

a) Non-discrimination: any requesting Customer may access certification services in accordance with this regulation, without any discrimination based on commercial or financial grounds or membership of specific organisations.

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

- Certification activities are assigned to personnel who do not have a vested interest in the Customer and/or in the activities/products subject to certification, who shall comply with the rules of conduct, impartiality and independence established by Kiwa Cermet. Therefore, Kiwa Cermet agrees to accept any justified reports by the Customer within 3 days of the notification of names, concerning conflicting tasks that may compromise the impartiality or independence of judgment;
- Exact application of official rules and procedures used by the certification service personnel and periodic consultation with relevant certification stakeholders;
- Clear separation between the personnel carrying out conformity assessment and the personnel responsible for decisions about certification;
- Avoiding any support to define and apply the requirements to obtain and maintain certifications.

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

d) Confidentiality: in addition to what is provided for in the *General Terms and Conditions* and *Kiwa Regulation for Certification*, all data and information of customers are treated with the utmost confidentiality, except as otherwise required by law. Moreover, Kiwa Cermet requires all 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 confidentiality is guaranteed by Control bodies and Competent and Designating authorities, for which Kiwa Cermet shall grant access to Customer's data. Information confidentially exchanged among Competent authorities and between Competent authorities and the European Commission is not disclosed, unless the Authority that transmitted it previously agrees upon. Confidentiality obligations do not impair the rights and duties of the Commission, Member States and Notified Bodies with regard to 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 may exchange confidential information with the regulatory Authorities of non-EU countries with which they entered into bilateral or multilateral confidentiality agreements.

e) Notification: Kiwa Cermet undertakes to inform the Customer of any waiver, reduction, suspension or withdrawal of the ministerial notification; in such cases, Kiwa Cermet informs the involved Customers, complies with the provisions of the responsible authority and to the maximum of its capabilities helps Customers transfer to another NB. Kiwa Cermet shall not be responsible for any damage caused to Customers as a result of the waiver, reduction, suspension or withdrawal of the notification. In the aforementioned cases, the Customer shall be entitled to terminate the agreement with Kiwa Cermet without notice or additional charges.

f) For outsourced activities, Kiwa Cermet undertakes to inform the Customer of the involved subcontractors.

[4] "Designating Authority" means the authority or authorities entrusted by a Member State with assessing, appointing, notifying and monitoring NBs pursuant to reference standards. Ref. website https://ec.europa.eu/growth/tools-databases/nando

3. REQUIREMENTS FOR CERTIFICATION AND ITS MAINTENANCE

3.1 General Requirements

Before starting the Certification process with Kiwa Cermet and in order to maintain the certification thereafter, the Customer shall meet the following requirements:

a) Meet the requirements provided for in the applicable standards and comply with the relevant provisions, with reference to Article 120 (2 and 3 c) of the MDR;

b) Accept and comply with the conditions set out in this regulation;

c) Accept to be subject to conformity assessment activities defined by Kiwa Cermet, referred to in or for the appropriate surveillance;

d) Suitably support Kiwa Cermet personnel in performing conformity assessment activities, including access to all premises being assessed during the audit (e.g. design premises, manufacturing premises, warehouses, etc.), to necessary documents and reports (including reports of internal audits and records for complaint resolution), to the personnel involved in the processes subject to certification and provide all necessary information, means and aids (including translators/interpreters choosen by the Customer at its expense) during assessment activties;

e) Appoint its own representative as the main contact person of the Audit Team and allow any consultants to be just an observer during the audit;

f) Be responsible for applying the requirements provided for by the applicable law on safety in the workplace. The Customer undertakes to provide Kiwa Cermet with a complete and detailed report of the specific risks that exist in the workplace where Kiwa Cermet personnel shall work. Therefore, the Organisation shall provide Kiwa Cermet personnel with the company documents of workplace safety (risk assessment document, safety plan, procedures, etc.) limited to aspects of specific interest and necessary PPE, informing Kiwa Cermet personnel of their proper use. If injuries occur or illnesses are contracted due to such omissions, no charges shall be pressed against Kiwa Cermet for any reason;

g) Accept, without additional costs, any personnel of the Control body/Designating authority as Observers, which shall be notified by Kiwa Cermet through a clear description of their roles. Their presence aims at assessing that the evaluation methods used by Kiwa Cermet comply with the notification requirements.

h) Accept any Additional Assessments (as defined in paragraph 4.6) which may be necessary under paragraph 4.6 and/or any requests for changes resulting from any decision of the Designating Authority, Competent authorities and the European Commission.

i) Provide all documents to be assessed by Kiwa Cermet and the relevant correspondence with Kiwa Cermet in Italian or English. No other languages shall be accepted. The Italian version shall always prevail in case of documents in English or in two languages and inconsistencies between the Italian and English version. Such documents shall be provided in an electronic noneditable format and shall be dated and signed. Any change to the content of documents to be assessed shall be marked and visible to promptly trace it compared to the previous revision. Such change management method shall be officially included in the Customer's quality management system.

j) Agree to adjust MDs and/or quality management system to any changed standards applicable to this regulation, after being informed by Kiwa Cermet and according to the terms defined by Kiwa Cermet.

3.2 Description and Classification of results of conformity assessment activities

Results of the document analysis are defined as follows:

Critical finding: non-compliance with a *certification requirement*[5] in technical documents and/or procedures of quality management system regarding the MD subject to certification, which prevents the MD or quality management system from achieving the expected results and therefore impairs product's safety, basic performance, technical features or functions.

[5] It refers to all regulatory, legislative, contractual requirements and reference specifications applicable to the certification referred to in this regulation.

Non-critical finding: non-compliance or partial compliance with a *certification requirement*[5], which needs a correction, but does not prevent the MD or the relevant quality management system from achieving the expected results and does not therefore fall within critical findings.

Audit results are defined as follows:

Major non-conformity (NC): non-compliance with a *certification requirement*[5], which prevents the MD or the relevant quality management system from achieving the expected results and therefore impairs safety, basic performance, technical features or functions of the product and/or quality system. Such finding may also result from numerous minor NCs regarding the same requirement/process.

Minor non-conformity (NC): non-compliance or partial compliance with a *certification requirement*[5], which needs a correction, but does not prevent the MD or the relevant quality management system from achieving the expected results and does not therefore fall within the abovementioned major non-conformities.

Minor non-conformities which are not resolved and/or not addressed by the Customer may result in a major NC.

Opportunity for improvement: what does not fall within the definition of NC and represents 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. Presumption of Conformity

Kiwa Cermet performs its activities in accordance with all requirements with which a Notified Body shall comply, as provided for by the Designating Authority nationally.

Medical devices compliant with relevant harmonised standards (including monographs of the European Pharmacopoeia) or relevant parts of such standards, whose references are published in the *Official Journal of the European Union,* are supposed to comply with Directive provisions.

Hence, Kiwa Cermet shall carry out the activities referred to in this regulation pursuant to MDD, applicable MDR provisions, relevant national regulations[6] and all abovementioned reference documents applicable to medical devices sector.

Upon receipt of the conformity assessment application pursuant to Article 120 (3 e) by Kiwa Cermet, the appropriate surveillance agreement shall be executed pursuant to provisions under paragraph 4.1.4. See also paragraph 4.5.2 on agreement execution regarding the assessment of non-significant and substantial changes.

4.1.2 MD classification

During the review of conformity assessment application[7] lodged by the Customer, Kiwa Cermet shall verify the intended use and the classification assigned by the Customer, who is responsible for it, as provided for in MDD Article 1 and Annex IX, respectively.

If the Customer and Kiwa Cermet do not agree upon the application of classification rules, Kiwa Cermet shall inform the Organisation; the Organisation is responsible for informing the Competent authority in which the Organisation is based, of such disagreements and the Competent authority shall make a decision. If the Organisation is not based in the European Union, the issue is submitted to the Competent authority of the Member State in which the authorised representative is based. If the Organisation is located in a Member State other than Italy, the Competent authority of the Organisation's Member State shall adopt a decision after consulting with the Italian Competent authority.

4.1.3 General rules for conformity assessment procedures

Conformity assessment procedures pursuant to Article 120 (3 e) of the MDR include activities described in paragraphs 4.2 to 4.5, and are carried out by Kiwa Cermet in accordance with the requirements applicable to conformity

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

[7] In compliance with the applicable regulations which do not allow to proceed with new applications for the certification of MDs pursuant to the Directive, this provision shall apply solely with reference to the assessment activities falling within the appropriate surveillance, including the application for non-significant and substantial changes to certification, pursuant to Article 120 (3 c) of the MDR.

assessment annexes selected by the Customer (during initial certification and/or renewal) and reported in valid MDD certificates pursuant to Article 120 (2) of the MDR.

Kiwa Cermet may perform the following conformity assessment activities:

- Whole Quality assurance system according to Annex II of the Directive;
- Production quality assurance according to Annex V of the Directive;
- Product quality assurance according to Annex VI of the Directive.

For class I sterile MDs with a measuring function Kiwa Cermet restricts its conformity assessment activities to maintenance of sterile conditions and compliance with metrological requirements, as provided for in the Directive.

For all devices to which other regulations or directives (e.g. Directive 2006/42/EC, Directive 89/686/EEC) may apply, the Organisation shall also refer to the requirements specified in such documents.

The following rules shall apply to any audit described hereinafter:

- The language of the audit shall be Italian or English; for other languages the Organisation shall provide translators supporting the audit team at its expense.
- After each audit the Conformity assessment team meets to assess the recorded evidence and their classification as well as to draw up a report.
- At the final meeting the Conformity assessment team submits the audit results and conclusions about the compliance of the Management System applied to the Directive to the Top Management and lists any recorded Non-conformities. After the meeting the Lead Auditor draws up a report describing the audit results.
- Any disagreement on audit results or conclusions between the Conformity assessment team and the Customer shall be addressed and settled, where possible. In case of any unsettled disagreement, the Customer may express some reservations about audit results. In this case the Customer shall write its reservations (on headed paper) by specifying the reasons for them; reservations shall be signed by the top management or their authorised representative. Kiwa Cermet shall address such reservations according to an internal procedure to determine whether to accept such reservations. After analysing them, Kiwa Cermet shall inform the Customer of the results. During the evaluation of such appeal and if Kiwa Cermet rejects reservations, the Customer shall implement what resulted from audit results.
- If NCs are recorded, the Customer shall define and implement suitable measures describing the root cause analysis, the management and the relevant corrective actions and specify methods and timing of implementation in a detailed plan. The Customer shall inform Kiwa Cermet of such corrective action plan (hereinafter referred to as "Corrective Action Plan or CAP") within a reference period as indicated in the following paragraphs.
- Opportunities for improvement shall be analysed by the Customer who may take relevant actions to implement them. If the Customer does not accepts such opportunities for improvement, he/she shall record the analysis anyway and the reasons for not implementing them. In this case Kiwa Cermet reserves the right to examine such opportunities in depth.

At any time Kiwa Cermet is entitled to send any notification/communication and forward any document, detail information and explanation regarding the Devices, the activities to be performed under this regulation as well as the resulting measures (e.g. suspension, withdrawal, reduction of the MDD certificate) to the competent and/or designating authorities, local and national authorities as well as EU and international authorities through the means of communication provided for by/required by such authorities, including any notification/communication regarding vigilance and in compliance with its obligations to inform pursuant to MDR, if the Devices and/or the management system subject to certification are not compliant.

4.1.4 Request for conformity assessment of MDs to Kiwa Cermet for the appropriate surveillance

4.1.4.1 Request for a quotation of appropriate surveillance by Customers

In order to request and receive a quotation[8], the Customer shall send to Kiwa Cermet information and documents required by Kiwa Cermet regarding the MDs that shall benefit from the Transitional Period, and shall request the relevant appropriate surveillance under Article 120 (3 e) of the MDR.

[8] Such request refers to Kiwa Cermet's Customers whose conformity assessment agreement pursuant to MDD has expired, or Customers which do not have a MDD certificate issued by Kiwa Cermet and entered into a conformity assessment agreement pursuant to MDR.

In particular, the Customer shall always attach

- the statement letter in which the Customer declares that with reference to each MD subject to the activities under this regulation, all conditions under Article 120 (2 and 3 c) of the MDR are met to benefit from the Transitional Period (ref. Customer's statement[9]: "Q&A on practical aspects related to the implementation of Reg. (EU) 2023/607"[10], Part B, point 7);
- copy of the quality system certificates or CE or EU certificates of the Critical Suppliers (if any).

Moreover, if the Customer requests a transfer of appropriate surveillance of MDs covered by MDD CE certificates issued by another NB (hereinafter referred to as "NB/MDD"), the Customer shall fill in and return to Kiwa Cermet the relevant form (MOD 09 MED_MDD) which is sent to it by Kiwa Cermet, in which the following information are required besides what is mentioned above:

- status of MDD certification validity with attached CE certificates issued by the NB/MDD;
- status of previous conformity assessment activities carried out by the NB/MDD, especially the date of the last assessment activity;
- critical suppliers.

If the Customer did not enter into a written agreement with Kiwa Cermet pursuant to Annex VII, section 4.3, subparagraph 2 to the MDR (hereinafter referred to as "MDR Contract") for the conformity assessment of MDs subject to appropriate surveillance and/or medical devices intended to replace them, the Customer shall also send to Kiwa Cermet:

a) if the MDD certificate of the MD subject to appropriate surveillance has not expired or expired on March 20, 2023 or after such date, the confirmation letter (hereinafter referred to as "Confirmation Letter") issued by another NB, stating that pursuant to Article 120 (3 c, letter (e)) of the MDR the Customer lodged or shall lodge a formal application for conformity assessment of such MD or a medical device intended to replace it by May 26, 2024, and signed or shall sign the MDR Contract by September 26, 2024. Such Confirmation Letter shall be given to Kiwa Cermet – also through additional documents to the appropriate surveillance agreement which may have been entered into between the Customer and Kiwa Cermet – as soon as the conditions for issuing the letter are met and, in any case, by the abovementioned dates in point (a);
b) if the MDD certificate of the MD subject to appropriate surveillance expired before March 20, 2023, (i) the Confirmation Letter stating that the Customer lodged a formal application and signed the MDR Contract before the expiry date of such certificate, or (ii) the derogation from the applicable conformity assessment procedure pursuant to Article 59 (1) of the MDR, or (iii) the authorisation under Article 97 (1) of the MDR to perform the conformity assessment procedure; for both cases in points (ii) and (iii) such documents are issued by the Competent authority of the reference EU Member State.

If the Customer requests a transfer of appropriate surveillance of Legacy Devices with CE certificates issued by another NB/MDD to Kiwa Cermet, the Customer shall enter into an agreement with Kiwa Cermet and, if possible, with the NB/MDD; such agreement shall establish the arrangements and terms for such transfer (hereinafter referred to as "Transfer Agreement", ref. Article 1 of Regulation 2023/607 and "Q*&A on practical aspects related to the implementation of Reg. (EU) 2023/607"* Part D, points 13 and 14"), which especially include the transfer date (hereinafter referred to as "Transfer Date").
The Customer is responsible for providing Kiwa Cermet with any required document and information within the due dates set by Kiwa Cermet (including those mentioned in the subsequent paragraph 4.7) in order to execute the Transfer Agreement and transfer the appropriate surveillance of MDs.

4.1.4.2 Issue and acceptance of the quotation of appropriate surveillance

Based on the collected information and documents Kiwa Cermet prepares the economic quotation of appropriate surveillance (including the Transfer Agreement, if applicable) which describes the provided service and specifies all information about activities and prices according to applicable fees.

In the event that from the received information any aspects emerge due to which Kiwa Cermet cannot ensure the performance of the activities or from which it can be inferred that the Customer does not meet the MDR requirements to benefit from the Transitional Period, Kiwa Cermet shall inform the Organisation that Kiwa Cermet cannot issue the quotation, specifying the reasons for it.

[9] Downloadable from the following link: *https://health.ec.europa.eu/medical-devices-sector/new-regulations_en*
[10] Available and downloadable from the following link *https://health.ec.europa.eu/latest-updates/qa-practical-aspects-related-implementation-regulation-eu-2023607-extension-mdr-transitional-period-2023-03-28_en*)

For the transfer of the appropriate surveillance from another NB to Kiwa Cermet it is agreed that the validity of Kiwa Cermet's quotation of appropriate surveillance depends on the entry into the Transfer Agreement.

The acceptance of the quotation by the Organisation[11] establishes the contractual relationship between the parties and represents the formal application (hereinafter referred to as "Application") for the appropriate surveillance.

4.1.4.3 Application review and confirmation of the activation of the appropriate surveillance process

Upon receipt of the Application (including the signed quotation, all required documents and, if applicable, the signed Transfer Agreement, including the documents mentioned in the following paragraph 4.7) from the Organisation, Kiwa Cermet reviews all documents and verifies that:

- All required data and documents are complete;
- The Transfer Agreement (in case of the transfer of the appropriate surveillance) is signed by all parties (Kiwa Cermet, Customer, NB/MDD, except for case of impossibility);
- The certification requirements are clearly defined and understood by both parties;
- Kiwa Cermet can perform the requested activities (including available sufficient and suitable resources);
- The data provided when requesting the quotation and/or Customer's statements in the quotation are consistent.

If the outcomes of the abovementioned review are successful, the service of appropriate surveillance begins.

If the outcomes are unsuccessful, Kiwa Cermet is entitled to request all necessary additions or amendments before officially starting the process, or inform the Organisation of the impossibility to start the process, by providing any reasons for it. If the negative outcome results from technical reasons or reasons related to product safety or the non-compliance of MDs with the requirements under Article 120 of the MDR or the failure to enter into the Transfer Agreement (as provided for in the previous paragraphs), Kiwa Cermet shall reject the Application and explain the reasons for it to the Organisation as well as inform the competent authority of the rejection through the means of communication required by it.

If the Organisation requests the application withdrawal, such request shall be considered a withdrawal from the appropriate surveillance agreement by the Customer (therefore, the Customer shall abide by the provisions referred to in Article 9) and such withdrawal shall be notified to the Competent authority through the means of communication required by it.

In case of the transfer of the appropriate surveillance it is specified that the Application review under this paragraph also includes a pre-transfer document analysis pursuant to paragraph 4.7.

4.2 Planning of conformity assessment activities

Conformity assessment activities for appropriate surveillance may include:

1. Planned annual surveillance audits;
2. Unannounced audits;
3. Assessments of the changes to MDs and/or the relevant quality management system which do not significantly affect MD design and intended use pursuant to Article 120 (3 c) of the MDR;
4. Additional assessments, including short-notice audits;
5. Transfer of surveillance from another NB/MDD.

Activities may be assigned to both employees and qualified external collaborators according to the requirements set in the reference documents and Kiwa Cermet procedures.

If part of the certification process shall be outsourced, Kiwa Cermet shall take all necessary measures to ensure that the outsourcing complies with the reference documents and Kiwa Cermet system documents. Kiwa Cermet is responsible for any outsourced activities.

4.3 Planned annual surveillance audits

Annual surveillance audits are carried out in order to:

[11] It means *Manufacturer* under Article 1 letter f of the MDD, for the contract (certification application) can only be signed by the Manufacturer.

- Verify that the MDs covered by MDD certificate continue to comply with relevant Directive;
- Verify that there are no significant changes in MD design and intended use pursuant to Article 120 (3 c), point (b)) of the MDR;
- Verify that the quality management system continues to be compliant and to ensure compliance of the MDs it covers, with MDD requirements as well as the applicable provisions pursuant to Article 120 (3 d) of the MDR;
- Verify that the quality management system is effectively and efficiently applied;
- Verify the compliance with the provisions of this regulation.

Surveillance audits are performed yearly (every 12 months after the previous surveillance audit, considering that the first surveillance audit shall be carried out within and no later than 12 months as of the date in the MDD certificate) and are based on sampled activities subject to certification with regard to the reference requirements for certification maintenance and on the performance of the Organisation's quality management system. Such audits generally include an on-site audit and a document analysis, including the update of clinical data, as described in paragraphs 4.3.1 and 4.3.2.

Kiwa Cermet shall contact the Customer to plan the activities. Once the dates are set, Kiwa Cermet Lead Auditor forwards the detail plan of activities to the Customer close to the scheduled dates for such audits and within 4 working days before the scheduled date.

The assessment of the provisions under Article 120 (3 d) of the MDR may require Additional Assessments (as defined in paragraph 4.6) compared to the quotation accepted by the Customer (e.g. PSUR, PMCF, etc.). During planning Kiwa Cermet shall yearly inform the Customer of the necessary additional time that results from the periodic sampling programme and is invoiced according to the pricelist in the quotation.

Before the surveillance audit Kiwa Cermet shall request the following updated documents: technical documents, quality management system procedures, documents relating to the update of clinical data, including PSUR and PSR, if applicable. Such documents shall be provided at least 30 days before the date of the audit, unless Kiwa Cermet schedules otherwise.

The Customer shall keep an updated copy of the technical file and the Quality Management system documents for Kiwa Cermet and make such copy available during assessment activities and throughout the validity of the assessment agreement with Kiwa Cermet.

The performance of surveillance audits is subject to the regular payment of previous activities by the Organisation. If the Organisation fails to fulfill its payment obligations, Kiwa Cermet reserves the right not to carry out the planned activities and suspend or withdraw the certificate.

4.3.1 Document analysis, including the update of clinical data

The document analysis is usually carried out at the same time as planned surveillance audits and *on-site* or *off-site*, based on the scheduling of activities.

The documents relating to clinical data are assessed close to or at the same time as the planned surveillance audit, if possible, but the assessment is not normally perfomed at the Organisation's premises.

For class III devices and implantable devices, Kiwa Cermet shall also assess the periodic safety update report (PSUR) according to the frequencies set out by MDR and draw up a report to be uploaded in EUDAMED[12]; the Organisation is responsible for providing to Kiwa Cermet such PSUR that shall be drawn up and updated according to Article 86 of the MDR and the available and relevant guidelines (e.g. MDCG 2022-21), based on the class of the Device subject to certification.

Any NC resulting from the document analysis shall be notified to the Organisation in the audit report and managed according to the methods indicated in paragraph 4.3.2.

As to findings resulting from the analysis of clinical data, Kiwa Cermet shall send the finding management form (MOD FT 01 MED) to the Customer, both in non-editable signed and editable format to manage the CAP; it is specified that an Additional Assessment is needed for such findings to approve the CAP and subsequently verify the resolution of implemented corrective actions which shall be :

[12] Until the date of the complete application of EUDAMED the Customer shall make the PSUR available close to the date of the surveillance audit upon request by Kiwa Cermet which shall make its PSUR evaluation available to the competent Authorities, the European Commission and the Designating Authority upon request.

1. in case of critical findings: within 3 months of receipt of the findings by the Organisation,
2. in case of non-critical findings: within a year of receipt of the findings by the Organisation, but in any case before the next annual surveillance document analysis.

Kiwa Cermet may define different timeframes depending on the findings and the necessary actions for their resolution.

In any cases, if the Customer fails to send the CAP to Kiwa Cermet within the abovementioned timeframes, Kiwa Cermet is entitled to suspend certification activities.

4.3.1.2 Complete document analysis

For MDs subject to document sampling within the certification process for the first time, the document analysis shall be carried out in accordance with the methods described in paragraph 4.3.1 according to Kiwa Cermet periodic programme, but the activities shall include the analysis of the complete technical file[13] and the Quality management system procedures which are significant for the audited MDs; such analysis aims at verifying the compliance with all applicable Directive requirements, including the Essential Requirements referred to in Annex I, and the applicable MDR provisions as well as the applicable provisions of national legislations. Special attention shall be given to solutions adopted during design, manufacturing, packaging, labelling and usability of MDs and their relevant risks.

Documents relating to preclinical data and test reports shall also be analysed. The tests provided by the Organisation shall be carried out in ISO 17025 accredited external laboratories, or Test Centres authorised for Good Laboratory Practices (GLP), or test centres recognised by scientific bodies of proven authority. The use of other laboratories is accepted, if the laboratory has been adequately qualified by the Organisation on the basis of ISO 17025 requirements and draws up a test report with the minimum information required by ISO 17025. Kiwa Cermet reserves the right to request the execution of other tests, if deemed necessary for conformity assessment. Any costs associated with the additional tests shall be borne by the Organisation.

All clinical data shall be analysed, including the update from post-marketing surveillance activities.

Any NC resulting from the document analysis shall be notified to the Organisation in the audit report and managed according to the methods indicated in paragraph 4.3.2.

4.3.2 On-site audits

On-site audits is always performed at the sites where activities related to products subject to certification take place. Moreover, such audit includes the assessment of any Critical Supplier as defined in the periodic programme of conformity assessment. By defining the aspects to be verified, Kiwa Cermet chooses the Critical Suppliers to be audited. Based on the results of periodic audits as well, Kiwa Cermet may decide not to perform the audit at a Critical Supplier if:

1. the Critical Supplier is certified by Kiwa Cermet with reference to the schemes ISO 13485, Annex IX or XI of the MDR, Annex II or V of the MDD, or ISO 9001, for the processes/services it provides to the Customer (related to the MD to be certified)
2. the Critical Supplier is certified by another Accredited or Notified Certification Body for similar schemes referred to in the previous point and is properly monitored by the Organisation[14];

provided that there are no other elements that question the ability of the Critical Supplier to provide the Organisation with products/services complying with the required specifications.

During surveillance audits, the resolution of non-conformities in previous audits is evaluated, together with the implementation and effectiveness of the corrective actions taken by the Customer.

During such audits, Kiwa Cermet may carry out tests or have them carried out.

Kiwa Cermet may perform sampling and laboratory tests on the certified Device. To this effect, a suitable sample of final products shall be taken on site and examined, and the appropriate tests defined in the corresponding standard, or equivalent tests shall be performed. If Kiwa Cermet finds incosistencies between the sample taken from the manufactured devices and the specifications mentioned in the technical documents, Kiwa Cermet suspends or

[13] To be considered complete the technical file shall deal with at least the items listed in the GHTF document "*Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performances of Medical Devices* (STED)" in as much detail as possible, in addition to any other item required by the applicable European legislation during the conformity assessment (ref. www.imdrf.org/ghtf/ghtf-archives-sg1.asp) and the relevant annexes referred to.

[14] For 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.

withdraws the relevant certificate or imposes reductions/limitations (if applicable). Additional details concerning testing activities are described in paragraph 4.4.

After the audit, Kiwa Cermet Audit Team gives a copy of the audit report to the Customer, who signs it. The report shall be deemed confirmed, if no further communications are received by the Customer within 60 working days.

If any NCs emerge, the Customer shall send the CAP and the implemetation schedule to Kiwa Cermet Lead Auditor by using Kiwa Cermet suitable forms, within 20 working days after the closure of the audit. The Lead Auditor shall assess the proposed actions by accepting or rejecting them, and inform the Organisation within 15 calendar days.

If the Customer fails to send the CAP within the abovementioned timeframes, Kiwa Cermet is entitled to suspend certification activities.

The implementation and effectiveness of corrections and corrective actions referring to minor NCs are assessed by Kiwa Cermet during the next periodic surveillance audit. Based on the number and content of minor NCs, an Additonal Assessment may be necessary to close such findings (the related costs are borne by the Organisation), which may be performed within 6 monhs from the date of the NC or during the next periodic surveillance upon Kiwa Cermet decision. Kiwa Cermet shall inform the Customer.

For major NCs that may affect product safety, certification shall be suspended (reduced, if applicable). Moreover, for each major NC the implementation of corrections and corrective actions shall be evaluated through an Additional Assessment, in accordance with the methods established by the Lead Auditor (audits at Customer's premises and/or by means of document evidence, where possible). Such Additional Assessment shall be carried out within and no later than 6 months from the surveillance audit; beyond such timeframe Kiwa Cermet shall decide on subsequent actions. If the abovementioned Additional Assessment is successful, certification is confirmed. If the Customer fails to implement the agreed actions for the resolution of findings within the allowed terms, certification may be withdrawn by Kiwa Cermet.

It is specified that whenever a CAP is present, an Additional Assessment is always needed to approve the CAP and verify the resolution of implemented corrective actions for major and minor NCs, if the number and complexity require it as indicated above.

4.4 Unannounced audits

Kiwa Cermet performs unannounced audits at sites where activities related to the products subject to certification are carried out (such sites shall also include the premises of Critical Suppliers), at least once every 3 years, as required by Directive conformity Annexes and the European Commission Recommendation 2013/473/EU.

Kiwa Cermet may increase the frequency of unannounced audits, for instance when MDs have a high potential risk and/or are often non-compliant and/or specific reasons exist to believe that the MDs and/or the Customer are non-compliant.

In order to ensure the proper performance of unannounced audits, the Customer undertakes to provide Kiwa Cermet with information on the periods of the year (company holyday period, holidays, stops in production, etc.) in which the MDs subject to certification are not manufactured.

The Customer also undertakes to include, in the contracts governing the relationships with its Critical Suppliers, the prior authorisation for Kiwa Cermet to access the premises/plants in which the Supplier's activities are carried out. If a visa is required to carry out the audit at the Supplier, the Organisation shall provide an invitation letter with open dates of signature and visit (if legally applicable). Moreover, Critical Suppliers shall undertake to provide the Customer, who in turn shall promptly inform Kiwa Cermet, with information about the periods of the year (company holyday period, holidays, stops in production, etc.) in which they do not supply their services on behalf of the Organisation.

Kiwa Cermet Audit Team arrives at the sites where activities related to the products subject to certification are carried out and identify themselves by identification badges and identification letters. The Customer may contact Kiwa Cermet offices and request a copy of the identification letter to verify its authenticity.

During an unannounced audit, the following requirements are assessed:

a) Maintenance of conformity of the devices subject to sampling, with regard to the approved technical documents (analysis of the technical file) and the provisions of law;

b) Traceability of all used components and critical materials, in particular by comparing the correspondence between the purchased materials and the outgoing finished products;

c) Maintenance of conformity of the approved quality management system.

When carrying out unannounced audits, Kiwa Cermet checks a suitable sample of newly-manufactured MDs, preferably taken from the current manufacturing process at the time of the audit, in order to ascertain compliance with technical documents and the provisions of law, by means of tests as well.

Therefore, the Audit Team requests the relevant technical documents, including the previous testing protocols and their results. The test is performed in compliance with the procedure reported by the Customer in the technical documents, and may be carried out:

d) at the site of the Customer or Critical Supplier, directly by the designated personnel and under the supervision of the Audit Team, which shall also investigate the involvement of competent personnel, suitable premises and measurement tools calibrated by accredited calibration centres and therefore with a metrological traceability guarantee;

e) at Kiwa Cermet Laboratory or external laboratories qualified by Kiwa Cermet. In special cases, when tests include protocols that are not easy to perform, laboratories recommended by the Customer may be chosen, provided that the test is carried out under the supervision of a Kiwa Cermet technical expert.

If an external laboratory is used, samples shall be packaged and sent by the Customer to the laboratory as indicated by the Lead Auditor, ensuring the integrity of the sample packaging, without any alteration of it.

If inconsistencies between the sample taken from the manufactured MDs and the specifications mentioned in the technical documents occur, Kiwa Cermet suspends or withdraws the relevant certificate or imposes reductions/limitations (if applicable).

After the audit, the Lead Auditor gives a copy of the audit report to the Customer and files a copy of the records of the tests carried out on the day of the audit, compiled by the Customer's designated personnel and/or Customer's Critical supplier, who was in charge of testing.

If tests are carried out by an external laboratory, or the test results require longer timeframes than the days of the unannounced audit, the report shall only be closed by the Lead Auditor after the test results and sent to the Customer together with the test reports from the external laboratory. A non-completed copy of the report can be issued upon Customer's request.

The results of unannounced audits are managed according to the methods described in paragraph 4.3.2.

If the Customer or its Critical Suppliers refuses to be subject to an unannounced audit or to grant access to the premises to be audited, the Customer shall make the refusal official (on letterhead paper stamped and signed) and specify the reasons for which the audit is not performed. Kiwa Cermet reserves the right to consider the actions to be taken, which may lead to the suspension or withdrawal of certification. The Customer is promptly informed of the decisions.

4.4.1 Sampling from the market

Kiwa Cermet reserves the right to test the product by sampling certified Devices from the market or the Organisation.

Such sampling may be performed, if, for instance there are no products to sample during the unannounced audit or in case of complaints, reports or alleged product non-compliance, etc. in any other stage of the certification process.

The applicable procedures to carry out tests and manage the results are described in the previous paragraph.

4.5 Assessment of non-significant changes

4.5.1 Changes

Only non-significant changes to the certified Devices are accepted, provided that such changes fall within those allowed pursuant to Article 120 (3 c, point b) of the MDR and the document MDCG 2020-3.

Hence, if the Organisation desires to modify the Devices, it shall first (i) make sure that the planned changes fall within the abovementioned non-significant changes by applying Guideline MDCG 2020-3, and (ii) send a communication to Kiwa Cermet specifying the following information in order to request and evaluate the acceptability of such planned changes before their implementation by the Customer.

It is specified that any request for changes which is not notified in advance cannot be accepted during planned annual audits at the Organisation's premises.

The Customer shall send the abovementioned notice in writing to Kiwa Cermet in writing, specifying the following information:

- description and clear identification of the requested change with a comparison to the current situation (including

pictures, if necessary) and supporting documents;

- device/certificates to which the change refers (codes, model, etc.);
- reference technical file and relevant impact;
- no. of the reference MDD certificate;
- rationale to prove that the change is not significant by applying Guideline MDCG 2020-3;
- rationale to define the non-significant change as *substantial*[15] or *non-substantial* in accordance with NBOG 2014-3.

After receiving such notice and based on the received information and documents, Kiwa Cermet shall evaluate the acceptability of the planned change and act as follows:

a) if the change represents a significant change in design and/or intended use of the MD pursuant to Article 120 (3 c, point b) of the MDR, Kiwa Cermet shall inform the Customer that such planned change cannot be adopted and implemented in the MD;

b) if the change does NOT represent a significant change in design and/or intended use of the MD pursuant to Article 120 (3 c, point b) of the MDR, Kiwa Cermet shall inform the Customer that the planned change is feasible and specify the subsequent actions to be taken pursuant to MDD. In particular:

   - for *non-significant and substantial changes*, the Customer shall not adopt such changes without a prior evaluation and approval by Kiwa Cermet. The Customer shall submit an official request for change as per paragraph 4.5.2;
   - for *non-significant and NON-substantial changes*, the Customer may adopt such changes without any prior evaluation and approval by Kiwa Cermet, which shall send a specific communication specifying the terms to evaluate the implementation of such change during the next periodic surveillance activity in accordance with the planned sampling.

Here below are some of but not all the main *non-significant and substantial changes* regarding the quality management system and the approved MD which require a prior approval by Kiwa Cermet before their implementation by the Customer, once such changes are defined as non-significant pursuant to Article 120 (3 c, point b) of the MDR:

- changes to Customer's sites and manufacturing sites of Critical Suppliers;
- changes to the Organisation's structure and process interaction;
- internalisation/outsourcing of a process or part of it;
- elimination/addition of Critical Suppliers and changes to their activities already approved;
- changes to the production process/design (tecnologies, parameters, premises, equipment, etc.) and changes to sterilisation or special coating processes;
- changes to the MD, such as mode of action, operative principles, control mechanisms, energy sources, product specifications, sw, interfaces, shelf-life, packaging, raw materials such as derivatives of animal and human tissues and/or medicines or plant derivatives;
- limitations to the intended use of the MDs or clarifications;
- changes to the range of the MDs. Additional variants are acceptable, if they are included in a range already approved;
- changes to the company name and registered office of the Customer and/or its Authorised representative, company changes involving the Customer, change to the legal representative of the Customer or its Authorised representative.

[15] Any change which may affect expected safety and/or performance and/or conditions of use of the MD, the conformity of the quality management system of MDs related to the applicable Directive requirements, including the requirements referred to in Annex I which need a conformity assessment prior to the approval of the change by Kiwa Cermet. For a further in-depth analysis of substantial changes, refer to the document NBOG 2014-3 *"Guidance for manufacturers and notified bodies on reporting of design and changes of the quality system".*

4.5.2 Request for a quotation of the evaluation of non-significant and substantial changes

For non-significant and substantial changes the Customer shall fill in the information form prepared by Kiwa Cermet to request the evaluation and approval of the change.

Based on the information reported in the form, Kiwa Cermet prepares the economic quotation containing the description of the offered service and all information relating to the activities of conformity assessment to be carried out (including document analyses and/or on-site audits), and the prices determined in accordance with the applicable rates.

The acceptance of the quotation by the Organisation determines the execution of the agreement with Kiwa Cermet for the evaluation of non-significant and substantial changes and represents the official application for such service (hereinafter referred to as "Application for Changes"). After receiving the Application for Changes which includes the signed quotation and all documents required in the form of the request for the evaluation of changes, Kiwa Cermet shall review such documents and verify that:

- The required data and documents have been provided in a comprehensive manner;
- It is confirmed that the planned change is actually non-significant pursuant to Article 120 (3 c, point b) of the MDR;
- Kiwa Cermet is capable of carrying out the required activities (including the availability of sufficient and adequate resources);
- There are no differences compared to the data provided at the time of the quotation request.

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

If the result is negative, Kiwa Cermet is entitled to request any necessary additions or changes before the formal start of the change process, or communicate the impossibility to start, providing the Customer with the relevant reasons.

Moreover, if inconsistencies regarding statements in the information form emerge during the document analysis or the audit, the quotation may be subject to review by Kiwa Cermet.

Finally, if during document analyses and/or on-site evaluations it emerges that the change significantly affect the design and/or the intended use of the MD, it is no longer possible to complete the assessment process which shall be rejected. Kiwa Cermet shall be responsible for informing the Customer.

4.5.3 Document analysis of non-significant and substantial changes

The document analysis of the MDs subject to a non-significant and substantial change pursuant to Article 120 (3 c, point b) of the MDR shall be performed by Kiwa Cermet only after receiving the Application for Changes and the approval of the review of such Application carried out by Kiwa Cermet (see paragraph 4.5.2).

Such activity shall be planned according to what is established in the agreement by Kiwa Cermet, within the certification process, and aims at verifying that the changed MD and/or the quality management system continue to comply with the applicable Directive requirements and the additional MDR provisions as well as confirming that such change is non-significant pursuant to Article 120 (3 c, point b) of the MDR. The document analysis shall consist in evaluating the changed parts of the technical documents and/or procedures of the quality management system.

After the document analysis is completed, Kiwa Cermet sends to the Customer the report summarizing the results, with any findings recorded in the relevant finding management form (MOD FT 01 MED), which shall be sent both in non-editable signed and editable format.

In the event of any findings, the Organisation shall send the CAP together with the proposal and the implemetation schedule for their resolution to Kiwa Cermet by using the form (MOD FT 01 MED), within 20 working days from the date of receipt of the abovementioned report by Kiwa Cermet; if the Customer fails to send the CAP within the abovementioned timeframes, Kiwa Cermet is entitled to suspend the ongoing certification.

It is specified that an Additional Assessment shall always be performed by Kiwa Cermet to approve the CAP and after such approval. Such activity shall be planned by Kiwa Cermet which shall inform the Customer of its dates.

In the case of critical findings, it is not possible to plan and carry out the on-site audit, where necessary, if such findings have not been resolved and closed. In the case of non-critical findings, it is possible to plan and carry out the on-site audit, where necessary, but in any case, the closure of such findings shall be assessed before the resolution for the formal approval of the changes by Kiwa Cermet.

If the Customer refuses the abovementioned Additional Assessments, Kiwa Cermet cannot carry on with the certification change process and shall implement the subsequent actions under paragraph 4.6.

The closure of the findings resulting from the document analysis shall be completed within 1 year from the date of completion of the first analysis; beyond this time limit, Kiwa Cermet shall evaluate consequent actions to be taken, including for example an interruption of the certification change process. Such decisions may also be made depending on significant changes to the reference regulations or rules, regarding the state of the art of knowledge of the product subject to certification, or of any changes relating to the Organisation's processes or sites.

4.5.4 On-site audits to evaluate non-significant and substantial changes

On-site audit activities are managed following the same methods as those described in the paragraph 4.3.2, but the evaluations shall involve the parts of the quality management system subject to the request for changes.

If any NCs emerge during the on-site audit, they are managed as described in paragraph 4.3.2, provided that the closure of the findings shall be completed within 1 year from the date of completion of the first audit; beyond this time limit, Kiwa Cermet shall evaluate consequent actions to be taken, including for example an interruption of the certification change process. Such decisions may also be made depending on significant changes to the reference regulations or rules, regarding the state of the art of knowledge of the product subject to certification, or of any changes relating to the Organisation's processes or sites.

4.5.5 Approval of changes

In the event of a positive outcome of the activities to evaluate the changes described above, the change process shall continue with the subsequent resolution phase for the approval of the change.

In the event of a successful resolution, Kiwa Cermet shall not issue a new certificate or modify the existing one, but shall send a letter approving the change to the Customer; such letter shall not be understood as a supplement to the certificate, but represents a document that shall always be attached to the certificate as a proof of change approval.

In the event of an unsuccessful resolution, it shall not be possible to proceed with the approval of the change; such decision shall be formally communicated to the Customer.

During the change resolution process, Kiwa Cermet may deem it necessary to request clarifications from personnel who carried out the conformity assessments, from the Customer as well as to request further activities of Additional Assessments or additional data/documents.

If during the assessment and approval of changes the contract with the Customer terminates due to any reasons, the approval of changes cannot be completed. The Customer shall pay the activities carried out until that moment to Kiwa Cermet anyway.

Kiwa Cermet shall communicate the approval of the change to the Italian Ministry of Health.

4.6 Additional assessments, including short-notice audits

In addition to the provisions of the common certification process, Kiwa Cermet reserves the right to perform any additional assessments (on document and/or on-site) ("Additional Assessment"), if necessary.

Additional Assessments may be performed:

- in the cases indicated in paragraphs 4.3, 4.4, 4.5;
- for the reasons specified in *Kiwa Regulation for Certification*;
- for requests that have arisen during the certification change decision or during the approval of the periodic assessment reports;
- to authorise the placing on the market of products in stock;
- in case of received information pertaining to serious accidents, emergencies or malfunctions;
- in case of received reports or notices regarding non-compliant aspects related to certified medical devices.

Kiwa Cermet shall inform the Customer of the necessary additional time to perform the Additional Assessment.

The Additional Assessments also include audits with a short notice of 5 working days from the date planned for the audit; in this case, considering the potential difficulties for the Organisation to refuse the members of the audit team appointed by Kiwa Cermet, utmost attention shall be paid to their selection.

The Additional Assessments shall be charged to the Organisation and be performed by Kiwa Cermet based on the prices reported in the quotation signed by the Customer; moreover, they do not replace or modify the process and frequencies of periodic surveillance audits and shall be communicated in advance to the Organisation.

If the Customer refuses – or does not allow Kiwa Cermet to perform – the Additional Assessment and/or refuses to pay the considerations and costs for such Additional Assessment to Kiwa Cermet, Kiwa Cermet cannot proceed with the activities of certification maintenance or change (depending on the situation) and shall take subsequent actions, including certificate suspension, certification withdrawal or reduction and the subsequent communications to the Competent Authorities.

4.7 Transfer of the surveillance to another NB/MDD

The arrangements of the transfer of appropriate surveillance activities from the NB/MDD to Kiwa Cermet pursuant to Article 120 (3 e) of the MDR, are always agreed upon with the Organisation in the quotation and, if possible, with the NB/MDD in the Transfer Agreement pursuant to the provisions under the previous paragraph 4.1.4.2.

Upon signing the Transfer Agreement or soon after, in addition to the documents that Kiwa Cermet requires to the Customer pursuant to paragraph 4.1.4.1, the Customer shall also send to Kiwa Cermet the following documents:

1. Copies of the completed reports of the audits of first certification (or latest re-certification) and the latest report of the appropriate surveillance audit carried out by the NB/MDD;
2. Copies of the complete reports of the document analysis of first certification (or latest re-certification) and the latest surveillance, including the clinical data and post-marketing evaluations (including PSUR, PMCF, PSR and SSCP) carried out by the NB/MDD for all products subject to appropriate surveillance;
3. CAP and documents pointing out the management and the progress status (treatment, corrective actions) of the reported NCs;
4. Vigilance data and evidence of their management;
5. Received complaints;
6. Periodic audit programme and relevant sampling of the NB/MDD;

A pre-transfer document analysis shall be performed on the documents mentioned in paragraph 4.1.4.1 and mentioned above in addition and prior to the activities under paragraph 4.3. Based on the results of such analysis Kiwa Cermet shall decide whether the conditions are met to carry on with the appropriate surveillance assessments or it is necessary to review the appropriate surveillance agreement entered into with the Customer in order to adjust the assessment time and/or sampling and/or the relevant frequencies. If the conditions are met and the agreement is consistent, the activities under paragraph 4.3 may proceed.

If the conditions/possibilities to provide the service due to techncial or safety reasons of the product and/or if the necessary requirements under the MDR do not occur so that the Organisation benefits from the transitional period, Kiwa Cermet terminates the appropriate surveillance agreement and inform the Customer, Kiwa Cermet's Designating Authority and the Competent Authority of the Member State in which the Customer's registered office is located.

5. SUSPENSION, WITHDRAWAL OR REDUCTION OF CERTIFICATION

The certification may be suspended/withdrawn/reduced for the reasons already indicated in this regulations, in the accepted quotation, in *Kiwa Regulation for Certification* or upon request by the Organisation. Moreover, the certification may also be suspended/withdrawn/reduced in the following additional cases:

a. Serious reports from the market and/or Competent Authorities, or failure to promptly inform Kiwa Cermet of any actions by the public authority, and/or accidents or ongoing legal proceedings related to MDs subject to certification;
b. Implementation of changes relating to the product or quality management system approved or covered by certification, without informing in advance and, in the case of substantial changes, without the approval by Kiwa Cermet;
c. References to certification or use of Kiwa Cermet mark in such a manner as to deviate from the provisions of this regulation under paragraph 6;
d. Incorrect qualification or classification of the MDs;
e. Bankruptcy or cessation of business;

Based on the reasons that led to the suspension/withdrawal/reduction, Kiwa Cermet reserves the right to request to the Customer:

- in the most serious cases the recall of the products already placed on the market (including products in stock, whose amount shall be communicated to Kiwa Cermet by the Customer);
- for cases of withdrawal or reduction, the last lot placed on the market upon withdrawal or reduction of the MDs subject to such measures. The MDs that have not been placed on the market yet, with no. 0476[16] on the label, or with the identification number of the NB other than Kiwa Cermet which issued the MDD certificate[17] can no longer be placed on the market.

In the event of suspension/withdrawal/reduction/subsequent reinstatement, Kiwa Cermet shall notify the Customer in writing, identifying the MDs subject to the specific measure (which shall be limited in cases of reduction) and communicating the conditions that the Customer shall meet to remove the causes leading to the specific measure and the timeframe for doing so to restore the validity of the certification, i.e. terminating the suspension. Such communications are also sent to Kiwa Cermet's Designating Authority and the Competent Authority of the Member State in which the Customer's registered office is located and are recorded in the relevant databases, if existing and active (e.g. EUDAMED, NSIS).

If the certification is suspended, the Customer loses, for the duration of the supsension, its right to place on the market the MDs with CE 0746 mark, i.e. the mark of the NB other than Kiwa Cermet that isseud the MDD certificate, and refer to the certification and the relevant CE certiticate with any means of communication; the Customer shall also stop using all advertising material that contains relevant references and return any certification documents upon request by Kiwa Cermet.

The conditions for certificate reinstatement (including the necessary activities of Additional Assessments) shall be established by Kiwa Cermet according to the reasons that led to the suspension and based on the duration of such suspension. Except exceptional cases (approved by Kiwa Cermet or the Competent Authority), the period of suspension shall not last longer than 6 months. If the Customer fails to implement the actions indicated by Kiwa Cermet to reinstate the suspended certification, such certification shall be withdrawn or its scope of application shall be reduced, if applicable.

The certification withdrawal (that is to say the reduction in the cases where it refers to only some MDs subject to certification) causes the Customer, immediately form the date of such measure:

- to lose its right to refer to the certification and the CE Certificate and their advertising through any means of communication (leaflets, catalogues, web sites, etc.);
- to lose its right to affix the CE 0476 marking or the mark of the NB other than Kiwa Cermet which issued the MDD certificate of all MDs referring to such provision and their subsequent discontinued placing on the market with such marking.

The withdrawal of the certification implies the automatic termination of the agreement to which this regulation applies pursuant to Article 1456 of the Italian Civil Code (that is to say in the case of reduction the termination for the applicable parts to the MDs referring to such measure), without prejudice to payment of all due amounts, including the compensation for any damage suffered by Kiwa Cermet in any case.

The reduction of the scope of application shall be notified to the Customer in writing, by specifying the types of products for which the certification is no longer valid.

For Devices registered in the National Medical Devices Database of the Italian Ministry of Health, in the event of a reduction of the certification, the Customer shall promptly update the registration of the involved medical devices, according to the procedures provided for by the Ministry of Health. Moreover, if the device subject to certificate reduction, has been registered individually, the end date of placing it on the market shall be indicated for this device in the National Medical Devices Database.

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

6. USE OF CERTIFICATION, CERTIFICATE AND CE MARKING

The Customer shall use the CE marking No. 0476 by Kiwa Cermet as defined in Annex XII to the Directive.

[16] Ref. paragraph 6.
[17] In the case of a transfer of Appropriate Surveillance where Kiwa Cermet is the incoming NB/MDR pursuant to Article 120, 3 e of the MDR.

The following rules apply in addition to what is indicated in the quotation and *Kiwa Regulation for Certification*.

It is considered incorrect use of the certification or the certificate when a third party is misled, or led to misinterpret the nature, quality and origin of the Device. In particular, it shall be clearly specified that the certificate relates solely to the certified "product". Partial copies of the certificate are not allowed.

The CE marking is used incorrectly if:

- the marking is affixed to devices that do not comply with what is reported in the certificates, or whose certificates were withdrawn/suspended;
- the certificate has expired[18];
- the certification of the devices has been withdrawn/suspended/reduced;
- the application for a certification change of the devices has not been approved yet or has been rejected;
- the Customer has not implemented the changes requested by Kiwa Cermet.

If incorrect use of the certification, the certificate or the CE marking occurs, Kiwa Cermet withdraws the certification and notifies the Competent authority. In severe cases (e.g. unlawful marking, fraudulent use) Kiwa Cermet reserves the right to inform the Italian Public Prosecutor.

If the Customer transfers the appropriate surveillance activities to another NB/MDR other than Kiwa Cermet, but he/she continues to affix the CE No. 0476 mark on the products subject to certification, the Customer shall continue to comply with all abovementioned rules of the correct use of the CE No. 0476 mark.

7. **CUSTOMER'S OBLIGATIONS –** HOLD HARMLESS CLAUSE

7.1. Cu**stomer's obligations** for Annex II, V and VI to the Directive

The Customer shall:

- Provide Kiwa Cermet with all necessary information regarding the Customer, products or categories of products subject to certification and any Suppliers;
- Inform Kiwa Cermet of all sites in which the Device is manufactured/designed, especially if such sites do not correspond to the Customer's operational headquarters;
- Provide Kiwa Cermet with all necessary technical and quality management system documents to carry out conformity assessments;
- Abide by and enforce the obligations provided for in the applicable articles and the annexes of the Directive, in the provisions provided for in Article 120 of the MDR, including the provisions for placing MDs on the market and their putting into service pursuant to Article 120 (3 a and 3 c) of the MDR as well as in any national applicable legislative provisions;
- Ensure the registration/information procedures provided for by the local Competent Authority;
- Inform Kiwa Cermet of the periods of the year in which Customer's activities are suspended (e.g. manufacturing of certified devices, company holiday periods, etc.);
- Maintain the MD compliance with the applicable requirements of the Directive, the provisions under Article 120 (3 d) of the MDR and the relevant national legislative provisions[19];
- Fulfil the obligations imposed by the quality management system approved by Kiwa Cermet, and ensure its proper and effective functioning which guarantees the conformity of the MDs subject to certification. Such obligations also include the systematic updating of documents in line with legislative updates, guidelines and the state of art of the reference sector;
- Establish and implement a procedure to manage changes that affect the products subject to certification or the approved quality management system, providing communication to Kiwa Cermet, sending information relating to

[18] The certificates no longer valid with regard to the transitional period set forth in the MDR are also included.
[19] Italian Legislative Decree of 5 August 2022, no. 137 "*Provisions for the compliance of national regulations with the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices* [...]".

changes and receiving approval from Kiwa Cermet before implementing any non-significant and substantial changes (Article 120, 3 c, point b);

- Establish a procedure to manage claims and reports received from its own customers and stakeholders that affect the conformity of the devices subject to certification, ensuring their proper registration, including the performance of appropriate investigations and, where necessary, the adoption of corrective measures;
- Promptly inform Kiwa Cermet of all inconsistent cases reported by the Vigilance Authority and any suspension or withdrawal of authorisations, granting, ongoing judicial/administrative proceedings relating to the certification subject, except for the limitations set forth by the national applicable law;
- Establish and update a procedure for the evaluation of clinical data and post-sales clinical follow-up performed or planned in relation to the devices subject to certification, as provided for in Annex X to the Directive and the provisions under Article 120 (3 d) of the MDR. If no clinical investigation is performed, a due explanation shall be provided;
- Establish and constantly update a procedure to systematically assess the acquired experience on the devices in the post-production stage, including the provisions of Annex X to the Directive and the provisions under Article 120 (3 d) of the MDR, as well as provide the appropriate means to apply the necessary corrective measures;
- Promptly inform the Competent Authorities and Kiwa Cermet as soon as the Customer becomes aware of any accidents or potential serious risks associated with the MDs available in the territories of the European Union, as provided for in Articles 87 and 88 of the MDR; moreover, in the event of a serious accident, undertake to carry out all activities laid down in Article 89 of the MDR;
- Establish in the contracts with all Critical Suppliers (including critical subcontractors in downstream supply chain as well, if necessary) that Kiwa Cermet shall be entitled to access all sites in which the MDs subject to certification are manufactured or processed, during periodic and unannounced audits, as well as to access the relevant documents of such suppliers;
- Undertake to request to the Critical Suppliers and include in its own document system all technical and quality management system documents proving the compliance with the essential requirements and the application of the quality management system. If the Supplier's documents are protected by trade secrets which do not allow the Supplier to disclose them to the Customer, an objective explanation shall be available to support it and Kiwa Cermet shall evaluate such explanation with regard to the suitability of process trade secrets. However, such documents shall be available to Kiwa Cermet during the audit.

7.2 **Additional Customer's obligations –** hold harmless clause

The Customer shall also:

- Comply with the provisions under paragraph 3.1;
- For the transfer of the appropriate surveillance from Kiwa Cermet (that issued the MDD certificate) to another NB, pursuant to Article 120, paragraph 3 e of the MDR, ensure that such NB forwards the Transfer Agreement to Kiwa Cermet to enter into it by the three parties; in the case of a transfer of appropriate surveillance from Kiwa Cermet to another NB, the existing agreement between Kiwa Cermet and the Customer becomes ineffective from the effective date of such transfer established in the Transfer Agreement; the Customer shall pay to Kiwa Cermet all due amounts for the activities performed until such date;
- In any case of transfer of the appropriate surveillance – from or to Kiwa cermet – pursuant to Article 120, paragraph 3 e of the MDR, provide any document and information required by Kiwa Cermet within the terms set by Kiwa Cermet, in order to execute the Transfer Agreement and transfer the appropriate surveillance;
- Inform the stakeholders (e.g. competent authorities, designating authorities, NB other than Kiwa Cermet to which the Organisation lodged the application for the MDR Contract or with which it entered into such contract), through Eudamed as well, of any non-compliance with any of the conditions under Article 120 (3 c) of the MDR within and no later than 10 days from the date on which the condition at issue was not met. The Organisation shall hold Kiwa Cermet harmless and indemnified against any claim, request for reimbursement of damages or action of third parties deriving from or connected to the breach of such obligation to inform;
- Inform Kiwa Cermet of each Device with a MDD certificate issued by Kiwa Cermet for which the Customer desires to benefit from the Transitional Period (even when the Customer desires to request the appropriate surveillance to another NB pursuant to Article 120 (3 e) of the MDR). It is understood that, in any case, Kiwa Cermet shall be liable for the appropriate surveillance of the Device only from the first conformity assessment activity which shall be carried out by Kiwa Cermet under the appropriate surveillance agreement entered into between the Customer

and Kiwa Cermet; therefore, the Customer shall exonerate Kiwa Cermet from any liability and also hold Kiwa Cermet harmless and indemnified against any claim, request for reimbursement of damages or action of third parties, deriving from or connected to any placing of the Devices on the market that may have occurred prior to the first conformity assessment activity carried out by Kiwa Cermet under the abovementioned appropriate surveillance agreement.

8. COMPLAINTS, APPEALS AND DISPUTES

8.1 Complaints

The Customer may file a documented complaint regarding its relationship as to certification activities with Kiwa Cermet.

Such complaint may arise from issues encountered during the certification process, such as delays in completing the various stages and/or incorrect conduct by Kiwa Cermet auditors.

Complaints shall be sent in writing (any type of support is accepted) and describe the situation complained about in detail. Kiwa Cermet shall reply to confirm whether it accepts the complaint or not, if such complaint refers to activities for which Kiwa Cermet is not responsible.

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

Complaints are dealt with by personnel who are not involved in the activities subject to complaints.

Kiwa Cermet shall agree with the claimant on whether and to what extent the content of the complaint and its resolution should be made public.

The procedure to file a complaint is available on the website www.kiwa.it

8.2 Appeals

If the claimant is not satisfied with the response, or desires to appeal against Kiwa Cermet's decision about the certification service referred to in this regulation, a written appeal can be lodged.

The petitioner shall explain the grounds for the appeal and, where the appeal refers to a decision made by Kiwa Cermet (e.g. reporting a major non-conformity), it shall be lodged with Kiwa Cermet within 10 calendar days from the date of the notified decision.

Appeals are dealt with by personnel who are not involved in the activities subject to appeals.

After examining the appeal and requiring further information from the Customer, if necessary, Kiwa Cermet shall provide the petioner with a writtent response and notify any actions to be taken within 30 days from the date of the lodged appeal.

The procedure to lodge an appeal is available on the website www.kiwa.it

8.3 Disputes

Any dispute between the Customer and Kiwa Cermet shall be settled pursuant to Article 18, paragraph 1 of the *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders.*

9. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT

Kiwa Cermet may freely withdraw from this contract by giving written communication to the Organisation with a notice of six months from the date on which the withdrawal shall be effective. The withdrawal by Kiwa Cermet determines the withdrawal of the issued certification. In any case the Organisation shall pay to Kiwa Cermet the amounts due for the services received during the notice period, as established in the latest valid quotation.

If the Customer desires to withdraw from the contract, the unilateral withdrawal shall be compliant with the notice periods set forth in the *General Terms and Conditions* and *Kiwa Regulation for Certification.*

In particular, for a notice shorter than three months with regard to the scheduled conformity assessment and longer than two weeks, the Customer shall pay 50% of the amount related to the compensation provided for the subsequent activity under the contract. The conditions specified in the *General Terms and Conditions* shall apply for a notice shorter than two weeks.

Kiwa Cermet shall issue an invoice of the expenses of closing the certification file in accordance with the latest valid quotation.

10. UNILATERAL AMENDMENT OF THE CONTRACT

Kiwa Cermet reserves the right to amend and complete this regulation at any time. Any new clauses/amendments shall become effective from their written notification to the Customer. The new version of this regulation shall be available on Kiwa Cermet website (www.kiwa.it), in the section Contact>Contractual Documents.

If the Organisation does not accept the amendments, it may terminate the contract by giving written notice by registered letter with return receipt or certified e-mail within 30 calendar days, under penalty of forfeiture, from the day after the communication to Kiwa Cermet.

The termination shall become effective from the last working day of the month in which the Customer's notice is received.