



# REGULATION ON APPROPRIATE SURVEILLANCE OF LEGACY DEVICES UNDER REGULATION (EU) 2017/745

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Rev.	Summary of change	Date
3	The document coding has been modified. The activities no longer applicable after the expiry of the transitional period for the submission of the applications for appropriate surveillance have been removed, and the legislative references have been aligned. The management of non-significant changes and the relevant process have been aligned.	2026-03-06
2	Introduction of details on appropriate surveillance transfer, other changes to withdrawal.	2024-01-22

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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 Italia**”) and the manufacturer or authorised representative (hereinafter referred to as “**Manufacturer**” or “**Organisation**”) to provide the service of the appropriate surveillance of medical devices and **their accessories** (hereinafter referred to as “**MDs**” or “**Devices**”), pursuant to Article 120 (3 e) of Regulation (EU) 2017/745 and subsequent amendments<sup>1</sup> (hereinafter referred to as “**Regulation**” or “**MDR**”).

This regulation applies **only** to Legacy Devices<sup>2</sup> and their accessories (hereinafter collectively referred to as “**MDs**” or “**Devices**”) **which**:

- I. have a certificate issued by a notified body (hereinafter referred to as “**Notified Body**” or “**NB**”) pursuant to the Directive 93/42/EEC (hereinafter referred to as “**Directive**” or “**MDD**”) 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 **by Kiwa Italia**.

According to recently changed regulations, the **Legacy Devices** complying with the requirements under Article 120 of the MDR may benefit from the extension of the 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**”) **until 31 December 2027 (MDs of class III and IIb implantable) or 31 December 2028 (MDs of class Is/Im, IIa, IIb non-implantable and MDs of class I pursuant to the MDD but with “higher” class pursuant to the MDR).**

Please note that from 26 May 2021 it is not permitted to issue a new certificate pursuant to the Directive 93/42/EEC (MDD), nor the update or change of existing ones. The extension of the validity of a MDD certificate as per Art. 120 (2) of the MDR is directly applicable by law, if some conditions are respected, without the need to modify the expiry date on the certificate itself. Even if it is no longer possible to issue new certificates in accordance with the MDD, the MDD requirements, in addition to the applicable requirements of the MDR as per art. 120, continue to apply for the surveillance of the already certified MDD devices (Legacy Devices), and for the non-significant change requests.

Certificates issued before 26 May 2021, in accordance with the MDD, which currently fall within the Annex XVI of the MDR, are also extended as per Regulation 2023/1194, in accordance with the conditions set out therein.

Conformity assessment activities referred to in the appropriate surveillance **are** performed on MDs:

- a) by reason of and pursuant to the agreement entered into with the **Organisation**, which comprises: (i) the quotation accepted by the **Organisation**; (ii) this regulation<sup>3</sup> (iii) the *Kiwa Regulation for Certification*; (iv) the *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, as well as pursuant to the **Directive**, to the applicable European guidelines and to the sector regulations in their harmonised versions at the time of the performance of the **activities**.

The requirements provided for in this regulation constitute an integral part of the agreement entered into with Kiwa **Italia**. 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.

<sup>1</sup> **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 **amended 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 [...]; **moreover the Regulation EU 2022/2346 of 01 December 2022 is taken into account which establishes common specifications for groups of products which are not intended for medical use, listed in Annex XVI of the Regulation (EU) 2017/745 as amended by the Regulation EU 2023/1194 of 20 June 2023, with regard to the transitional provisions for certain products which are not intended for medical use, listed in Annex XVI of the MDR.**

<sup>2</sup> “Legacy Devices” shall mean devices which are covered by a certificate issued by a NB pursuant to Directive **93/42/EEC (hereinafter referred to as MDD) and 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.

<sup>3</sup> As to the existing agreements of the conformity assessment of MDs between Kiwa **Italia** and the **Organisation**, the updated **version of this Regulation** entirely and legally replaces and supersedes the previous version.

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

- **“Supplier”**: organisation or legal person external to the **Organisation** providing a product or a service in connection with the MD subject to certification that does not affect the safety and performance of such MD;
- **“Critical Supplier”**: organisation or legal person external to the **Organisation** 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.). Sub-suppliers in downstream supply chains are also included among such suppliers, if they are considered critical with regard to what stated above.

Product types of **Legacy Devices** on which Kiwa **Italia** is authorised to operate are listed in the notification of authorisation issued to Kiwa **Italia** by the Designating Authority<sup>4</sup>. From 26 May 2021 the validity of the publications of the notifications relating to Kiwa **Italia** as NB pursuant to the MDD (ref. Art. 120 (1) of the MDR) has ceased. However Kiwa **Italia**, in the capacity of NB designated under the MDR, continues to be responsible for the appropriate surveillance of the Devices certified pursuant to the MDD, provided that all conditions set out in the Article 120 of the MDR are met.

The subject matter of the agreement expressly excludes any form of consultancy to the **Organisation** that may jeopardise the independence of assessments performed.

This regulation is also available on **Kiwa Italia** website ([www.kiwa.it](http://www.kiwa.it)). **Organisations** who intend to enter into an agreement with **Kiwa Italia** may request an electronic copy.

**Kiwa Italia** shall also inform the **Organisation** of any subsequent amendments to contractual documents; the **Organisation** is responsible for having the latest version of such documents by downloading them from the website [www.kiwa.it](http://www.kiwa.it)

## 2. GENERAL PRINCIPLES AND GUARANTEES FOR THE ORGANISATION

**Kiwa Italia** applies the following principles, in addition to what is provided for in the *General Terms and Conditions*, to perform the activities of conformity assessment:

- a) Non-discrimination: any requesting **Organisation** 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 **Organisation** and/or in the activities/products subject to certification, who shall comply with the rules of conduct, impartiality and independence established by **Kiwa Italia**. Therefore, **Kiwa Italia** agrees to accept any justified reports by the **Organisation** within 3 days of the notification of names, concerning the existence of a conflict of interest 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.
  - Total abstention from carrying out any assistance activities related to the definition and application of the requirements to obtain and maintain certifications.
- c) Prompt management of complaints and appeals, as defined in § 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, documents and information of the **Organisation** are managed with the utmost confidentiality, except as otherwise required by law. Moreover, **Kiwa Italia** 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 compliance with the applicable privacy laws.

<sup>4</sup> **“Designating Authority”** means, in accordance with relevant legislation, the authority or authorities entrusted by a Member State with assessing, designating, notifying and monitoring NBs. Ref. website <https://ec.europa.eu/growth/tools-databases/nando>

A similar commitment concerning confidentiality is guaranteed by Control bodies and Competent and Designating authorities, for which Kiwa *Italia* shall grant access to *Organisation'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 *Italia* undertakes to inform the *Organisation* of any waiver, reduction, suspension or withdrawal of the ministerial notification; in such cases, Kiwa *Italia* informs the involved *Organisations*, complies with the provisions of the responsible authority and to the extent of its capabilities helps *Organisations* transfer to another NB. Kiwa *Italia* shall not be responsible for any damage caused to *Organisations* as a result of the waiver, reduction, suspension or withdrawal of the notification. In the aforementioned cases, the *Organisation* shall be entitled to terminate the agreement with Kiwa *Italia* without notice or additional charges.
- f) For outsourced activities, Kiwa *Italia* undertakes to inform the *Organisation* of the involved subcontractors.

### 3. REQUIREMENTS FOR CERTIFICATION AND ITS MAINTENANCE

#### 3.1 General Requirements

The *Organisation* that wants to maintain the validity of the MDD certificate during the transitional period, shall:

- a) meet the requirements provided for in the relevant Directive as well as the applicable regulations and provisions set out in Article 120 (2 and 3 c) of the MDR.
- b) Accept and comply with the conditions set out in this regulation.
- c) Accept to undergo the conformity assessment activities defined by Kiwa *Italia*, referred to in or for the appropriate surveillance, as set out in art. 120 of the MDR.
- d) Ensure all the necessary facilities to support Kiwa *Italia* 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 records (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 chosen by the *Organisation* at its own expense) during assessment activities.
- e) Appoint its own representative as the main contact person of the Audit Team and ensure that any consultants present during the audit act solely as observers.
- f) Be responsible for applying the requirements provided for by the applicable law on safety in the workplace. The *Organisation* undertakes to provide Kiwa *Italia* with a complete and detailed report of the specific risks that exist in the environment where Kiwa *Italia* personnel shall work. Therefore, the *Organisation* shall provide the personnel appointed by Kiwa *Italia* with the company documentation relating to workplace safety (risk assessment document, safety plan, procedures, etc.) limited to the aspects of specific interest and necessary PPE, informing Kiwa *Italia* personnel of their proper use. Where, due to such omissions, injuries occur or illnesses are contracted, no charges shall be brought against Kiwa *Italia* for any reason.
- g) Accept, without additional costs, the possible presence of personnel of the Control body/Designating authority acting as Observers, which shall be notified by Kiwa *Italia* through a clear description of their roles. The purpose of this presence is to assess that the evaluation methods used by Kiwa *Italia* 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 *Italia* and the relevant correspondence with Kiwa *Italia* 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 documentation shall be provided in a non-editable electronic 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 *Organisation's* quality management system.

- j) Agree, in the event of changes to the regulations applicable to this regulation, to adapt its MDs and/or its quality management system in accordance with such changes, following communication of – and within the defined terms by – Kiwa Italia.

### 3.2 Description and Classification of results of conformity assessment activities

Results of the documentary analysis are defined as follows:

**Critical finding:** non-compliance with a *certification requirement*<sup>5</sup> in technical documentation and/or procedures of quality management system regarding the MD subject to certification, which affects the ability of the MD or quality management system to achieve the expected results and therefore impairs product's safety, basic performance, technical features or functions.

**Non-critical finding:** failure to meet, or partial fulfilment of a *certification requirement*<sup>5</sup>, which needs a correction, but does not affect the ability of the MD or of the relevant quality management system to achieve 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*<sup>5</sup>, which affects the ability of the MD or of the relevant quality management system to achieve 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*<sup>5</sup>, which needs a correction, but does not affect the ability of the MD or the relevant quality management system to achieve 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 [Organisation](#) 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 of the product subject to certification.

## 4. REQUIREMENTS OF THE CONFORMITY ASSESSMENT PROCESS

### 4.1 General Requirements

#### 4.1.1. Presumption of Conformity

[Kiwa Italia](#) performs its activities in compliance with all requirements with which a Notified Body shall comply, as provided for by the Designating Authority nationally.

[Legacy 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 presumed to be in conformity with [the applicable provisions of the MDD and with those of article 120 of the MDR](#).

In carrying out the activities referred to in this regulation, [Kiwa Italia](#) shall operate in accordance with [the provisions of article 120 of the MDR and to the applicable provisions of the MDD](#), the relevant national legislative requirements<sup>6</sup> and to all the above-mentioned guidance documents applicable to the medical devices sector.

#### 4.1.2 Responsibilities for the appropriate surveillance of Legacy Devices

Until 26 September 2024, responsibility for the appropriate surveillance of the Device with a valid MDD certificate remains with the NB that issued such certificate (hereinafter referred to as “NB/MDD”), unless the Manufacturer decides (voluntarily) to transfer the responsibility for such surveillance to another designated NB pursuant to the MDR (hereinafter referred to as “NB/MDR”).

From 26 September 2024, responsibility for the appropriate surveillance of the device holding a valid MDD certificate is assumed by the NB, with which the manufacturer has entered into an agreement for conformity assessment pursuant to Ann. VII of the MDR (#4.3, paragraph 2), for that device or of a device intended to replace it. Therefore, if the NB/MDR is different from the NB/MDD, responsibility for the appropriate surveillance is transferred from the NB/MDD to the NB/MDR by the aforementioned date. Moreover, from this date onwards, the transfer of appropriate surveillance shall also take

<sup>5</sup> It refers to all regulatory, legislative, contractual requirements and reference specifications applicable to the certification referred to in this regulation.

<sup>6</sup> 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 [...]”.

place where the Organisation that signed the conformity assessment agreement pursuant to Ann. VII of the MDR (#4.3, paragraph 2) with a body other than the NB/MDR, which in turn is responsible for appropriate surveillance pursuant to article 120 of the MDR, decides to transfer the MDR certification application from that NB/MDR to another NB/MDR.

Therefore, in the light of the above, the terms and procedures for the transfer of responsibility for appropriate surveillance to Kiwa Italia shall be clearly defined as follows:

- the quotation issued by Kiwa Italia and signed by the Organisation, and the relevant contractual documents referred to therein;
- the trilateral agreement for the transfer of surveillance (hereinafter referred to as “Transfer Agreement”), entered into between Kiwa Italia, the Organisation and, if possible, the outgoing NB. This agreement details the responsibilities for the parties and the documents and information which shall be provided to Kiwa Italia to enable the transfer. Such trilateral agreement comes into effect as soon as it is signed by Kiwa Italia, the Organisation and, if possible, by the outgoing NB. In the cases where the signing by the outgoing NB is not possible, the agreement, signed by Kiwa Italia and the Organisation, nonetheless is considered valid for what concerns the terms and responsibilities of the two parties. In those cases and if possible, the terms for the transfer of the appropriate surveillance with the outgoing NB will be otherwise agreed (via email, certified email).

Procedures applicable in cases of transfer of the appropriate surveillance to Kiwa Italia, as NB/MDR, are detailed in paragraph 4.1.4.

In the event of transfer of the appropriate surveillance from Kiwa Italia, as NB/MDD to another NB/MDR, the existing Certification Agreement between Kiwa Italia and the Manufacturer ceases to have effects from the effective date of such transfer (hereinafter referred to as “transfer date”), set out in the aforementioned transfer Agreement. The Organisation is required to pay to Kiwa Italia the balance of all amounts due for the activities carried out by Kiwa Italia until the aforementioned date, including the amounts for the maintenance of the Certification as per the terms and periodicity set out in the Quotation and the penalties for the closure.

#### 4.1.3 General rules for conformity assessment procedures

Kiwa Italia may perform the conformity assessment of the appropriate surveillance pursuant to Article 120 (3 e) of the MDR for MDD certification processes carried out pursuant to the following annexes to conformity:

- Full Quality assurance system in accordance with to Annex II of the Directive;
- Production quality assurance in accordance with Annex V of the Directive;
- Product quality assurance in accordance with Annex VI of the Directive.

For class I sterile MDs with a measuring function Kiwa Italia 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 take into account the requirements set out in those 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 on a continuous bases to support 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 presents the audit results and conclusions regarding the compliance of the Management System applied to the Directive to the Top Management identifying any Non-Conformities found. After the meeting the Lead Auditor issues a report describing the audit results.
- Any disagreement on audit results or conclusions between the Conformity assessment team and the Organisation shall be addressed and settled, where possible. In case of any unsettled disagreement, the Organisation may express reservations about audit results. In this case the Organisation shall submit its reservations in writing (on the Organisation’s letterhead) by specifying the reasons for them; reservations shall be signed by the top management or their authorised representative. Kiwa Italia shall address such reservations according to an internal procedure to determine whether to accept such reservations. After analysing them, Kiwa Italia shall inform the Organisation of the results. During the evaluation of such appeal and if Kiwa Italia rejects reservation, the Organisation shall implement what resulted from audit results.

- If NCs are recorded, the **Organisation** shall define and implement appropriate plans describing the root cause analysis of the NCs, the treatment measures and the resulting corrective actions, with a clearly defined process specifying the methods and timelines for implementation. The **Organisation** shall inform Kiwa **Italia** of such corrective action plan (hereinafter referred to as the “Corrective Action Plan or CAP”) within a reference period as set out in the following paragraphs.
- Opportunities for improvement shall be analysed by the **Organisation** which may decide whether or not to define the related actions for their implementation. Where the **Organisation** decides not to follow up on an opportunity for improvement, it shall nonetheless record the analysis performed and the reasons for not implementing it. In such cases Kiwa **Italia** reserves the right to further investigate the reported matter.

At any time Kiwa **Italia** is entitled to send any notification/communication and forward any documentation, detail and clarifications regarding the Devices, the activities to be performed under the present regulation as well as the resulting measures (e.g. suspension, withdrawal, reduction of the **certificate**) to the competent and/or designating authorities, local, national authorities as well as European Union and international authorities, through the means of communication provided for by/required by such authorities, including any notification/communication, pursuant to MDR, regarding vigilance and in compliance with its obligations to inform, in the event of non-conformity of the Devices and/or the management system subject to certification.

#### 4.1.4 Request for conformity assessment of **Legacy Devices** to **Kiwa Italia** for the appropriate surveillance

In order to request the transfer of the appropriate surveillance to Kiwa **Italia** from another outgoing NB, the **Organisation**<sup>7</sup> shall complete, sign and return to Kiwa **Italia**, both in non-editable PDF format and in XLS format, the MOD PO 09 MED\_MDR\_AS\_Pre-information Sheet - Appropriate Surveillance & Changes form (hereinafter referred to as MOD PO 09 MED\_MDR\_AS), including all documentation required by the form itself where applicable. In particular, the following information and documents are always necessary:

- the self-declaration Letter in which the **Organisation** declares that with reference to each **Legacy Device** 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. self-declaration<sup>8</sup>: “Q&A on practical aspects related to the implementation of Reg. (EU) 2023/607”, Part B, point 7);
- the confirmation letter<sup>9</sup>, issued by the outgoing NB, or, alternatively, the MDR Agreement (in compliance with the Annex VII, point 4.3, paragraph 2, of the MDR), signed by 26.09.2024 with the outgoing NB, which attests that the **Organisation**, in compliance with Article 120 (3 c, letter (e)) of the MDR, has submitted a formal application for the conformity assessment of such **Legacy Devices** or of a medical device intended to replace them (such legacy devices shall be clearly identifiable in case of an MDR Agreement);
- the CE certificates valid under the transitional period, and any other document that has modified the status of the certificates (for example, Clearance Letter, appendices resulting from non-significant changes) issued by a NB other than Kiwa **Italia**;
- list of non-significant changes implemented from 26 May 2021 up to the submission to Kiwa **Italia**;
- instructions for use of legacy devices subject to the request;
- declaration of conformity of the legacy devices subject to the request and a list of all references.

In addition, the **Organisation** shall provide:

- detailed information regarding the status of previous conformity assessment activities carried out by the outgoing NB, in particular at least the date of the last audit carried out for appropriate surveillance and its results, including the status of any NCs and of the related ongoing corrective actions; the same information shall be provided for the last technical documentation assessments, including clinical data;
- detailed information regarding any ongoing changes at the time of the request for transfer of the appropriate surveillance to Kiwa **Italia**;
- information regarding any ongoing issues (for example, post-market reports and vigilance events).

In the event of missing documents or documents not correctly completed, Kiwa **Italia** will request the **Organisation** to provide the necessary additions which may also entail a revision of the MOD PO 09 MED\_MDR\_AS including an update of the date and signature by the **Organisation**.

Once all the aforementioned information has been fully received, Kiwa **Italia** will arrange a structured dialogue with the **Organisation** in order to further discuss and clarify on the procedures and timelines of the appropriate surveillance

<sup>7</sup> Or its Authorised Representative, if the **Organisation** is settled outside the European Union.

<sup>8</sup> Downloadable from the following link: [https://health.ec.europa.eu/medical-devices-sector/new-regulations\\_en](https://health.ec.europa.eu/medical-devices-sector/new-regulations_en)

<sup>9</sup> Where applicable, for expired certificates before 23/03/2023, the act of derogation to the conformity assessment procedure applicable as per art. 59, par. 1 of the MDR, or the authorization pursuant to art. 97 par. 1 of the MDR to perform a procedure of conformity assessment, in both cases these documents are issued by the competent Authority of the reference member state of the European Union.

transfer process, also with reference to the concurrent transfer of the application or certification in accordance with the MDR.

Following the above, in the event of a positive outcome of the review of the preliminary information, Kiwa Italia will issue the quotation for the appropriate surveillance and will forward it to the Organisation. This quotation sets out the service conditions, information on the conformity assessment activities to be carried out based on the information provided and the prices determined in accordance with the pricelist currently in force, available on Kiwa Italia's website.

It will also be necessary to enter into a specific "Transfer Agreement" between the Organisation and Kiwa Italia and, if possible, with the outgoing NB/MDD, including in particular the date of transfer (hereinafter referred to as "Transfer Date"). Kiwa Italia will draw up this "Transfer Agreement" using the following forms:

- "Agreement Related to the Transfer of MDR Formal Application and of Appropriate Surveillance of Legacy Devices" in cases where the transfer of appropriate surveillance takes place simultaneously with the transfer of a formal MDR certification application.
- The "Transfer Agreement for Surveillance of Legacy Devices", in cases where the transfer of the appropriate surveillance takes place simultaneously with the transfer of the MDR certification (EU certificate already issued).

The Organisation shall simultaneously sign the "Transfer Agreement" and the quotation drawn up by Kiwa Italia and shall inform the outgoing NB/MDD so that it too may sign shortly the "Transfer Agreement".

Once signed by the Organisation<sup>10</sup>, the quotation and the "Transfer Agreement" formalise the contractual relationship between the parties and constitute the official application (hereinafter referred to as "Application") for the activity of appropriate surveillance.

The Organisation shall be responsible for providing Kiwa Italia with each document and information required by the "Transfer Agreement" for the purpose of starting the appropriate surveillance transfer process of the Legacy Devices. Therefore, in addition to the documentation previously provided, the Organisation, or the outgoing NB/MDD, shall also send the following documents to Kiwa Italia:

1. complete audit reports from the initial certification (or from the most recent recertification) and the latest appropriate surveillance audit report, carried out by the outgoing NB;
2. complete documentary assessment reports from the initial certification (or from the most recent recertification) and the latest surveillance, including evaluations of clinical data and post-market data (including PSUR, PMCF, PSR and SSCP), carried out by the outgoing NB, for all the products subject to appropriate surveillance;
3. corrective actions plan and documentation highlighting the management and the status of progress (treatments, corrective actions) of recorded non-conformities;
4. vigilance data and evidence of their management;
5. received complaints;
6. the periodic audit programme and related sampling of the outgoing NB.

Kiwa Italia, once the signed Application and all the aforementioned documentation are received from the Organisation, carries out a review of the application (hereinafter referred to as "Pre-transfer"), as a preliminary step prior to the subsequent assessment activities set out in paragraph 4.3, verifying that:

- all required data and documents have been provided in full;
- the Transfer Agreement (in the event of the appropriate surveillance transfer) has been signed by all parties (Kiwa Italia, the Organisation, the NB/MDD, except in cases of impossibility);
- Kiwa Italia is capable of carrying out the requested activities (including the availability of sufficient and suitable resources);
- the scheduled days and activities are consistent with the information received;
- there are no differences compared to the data provided when requesting the quotation and/or to the statements made by the Organisation in the quotation.

During the Pre-transfer activities Kiwa Italia has the right to require all the necessary additions or modifications for its completion.

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<sup>10</sup> Intended as Manufacturer as per art. 1 letter f of the MDD, as the contract (application for certification) can only be signed by the Manufacturer.

Based on the outcomes of this analysis, Kiwa [Italia](#) will decide whether the conditions for proceeding with the assessments of appropriate surveillance are in place or whether it is necessary to review the agreement entered into with the [Organisation](#) for the appropriate surveillance in order to adapt the assessment duration and/or the sampling and/or the related frequencies. If the conditions are in place and the agreement is consistent, the activities will be carried out as per § 4.3.

In the event that the conditions/capacities are not in place for the provision of the service for technical or product safety reasons and/or where the necessary requirements, under the MDR, in order for the Organisation to benefit from the transitional period, are not met, Kiwa [Italia](#) withdraws from the appropriate surveillance agreement, [rejecting the Organisation's formal application](#), notifying the [Organisation](#), Kiwa [Italia](#)'s Designating Authority and the competent Authority of the Member State where the [Organisation](#) has its registered office.

Where the Organisation requests the withdrawal of the Application, such request shall be deemed as withdrawal by the [Organisation](#) from the appropriate surveillance Agreement (consequently, the [Organisation](#) shall comply with the provisions set out in Article 9 below) and the withdrawal will be notified to the competent Authority through the communication channels specified by that Authority.

[In both cases, of withdrawal of the application by Kiwa Italia or refusal by the Organisation, it is specified that the legacy devices subject to the application shall no longer meet one of the conditions set out in article 120 of the MDR and therefore shall no longer benefit from the transitional period.](#)

#### 4.2 Planning of the [appropriate surveillance activities](#)

Conformity assessment activities for appropriate surveillance may include:

1. planned annual surveillance audits;
2. unannounced audits;
3. assessments of changes to MDs and/or to the related quality management system which do have a significant impact on the MDs 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](#).

Activities may be assigned to both employees and qualified external collaborators in accordance with the requirements set out in the reference documents and in [Kiwa Italia's](#) procedures.

Should it become necessary to subcontract part of the certification processes, Kiwa [Italia](#) shall take all necessary measures to ensure that the subcontracting complies with the reference documents and Kiwa [Italia's](#) system documentation. Responsibility for any outsourced activities shall remain with [Kiwa Italia](#).

#### 4.3 Planned annual surveillance audits

Annual surveillance audits are conducted in order to:

- verify that the MDs covered by the 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 (in line with MDCG 2020-3);
- verify that the quality management system continues to be compliant and to ensure the conformity of the related MDs, [with the applicable provisions](#) pursuant to Article 120 (3 d) of the MDR;
- verify that the quality management system is applied effectively;
- verify the compliance with the provisions of this regulation.

Surveillance audits are performed annually (every 12 months after the previous surveillance audit) [and can be brought forward or postponed by 3 months with respect to the month of the CE certificate issuance \(hereinafter referred to as "Due date"\) at the sole discretion of Kiwa Italia; such activities](#) are based on a sampling of the activities subject to certification with respect to the reference requirements for maintain certification and the performance of the Organisation's quality management system. Such assessments generally consist of an on-site audit and, [where necessary, also](#) include an analysis of the [technical](#) documentation, including the update of clinical data, as described in paragraphs 4.3.1 and 4.3.2.

Kiwa [Italia](#) shall contact the [Organisation](#) in order to schedule the activities. Once the dates are set, Kiwa [Italia](#) Lead Auditor shall forward the detailed plan of activities to the [Organisation](#) in proximity to the scheduled dates for such audits and in any case no later than 4 working days prior to the scheduled date.

The assessment of the provisions pursuant to Article 120 (3 d) of the MDR may require Additional Assessments (as defined in paragraph 4.6) with respect to what is included in the quotation accepted by the [Organisation](#) (e.g. PSUR, PMCF, etc.). [Kiwa Italia](#) will be responsible for informing the [Organisation](#) annually, during the planning phase, of the additional time required, as determined on the basis of the periodic sampling programme, which shall be invoiced in accordance with the pricelist set out in the quotation [in force](#).

Prior to the surveillance audit, [Kiwa Italia](#) shall request the submission of the following updated documents: technical documentation, quality management system procedures, documents relating to the update of clinical data, including PSUR and PSR, where applicable. Such documents shall be provided at least 30 days prior to the audit date, unless different frequencies are approved by [Kiwa Italia](#).

The [Organisation](#) shall maintain a controlled and up-to-date copy of the technical file and the Quality Management system documentation for [Kiwa Italia](#) and shall make it available during the assessment activities and throughout the entire validity period of the assessment agreement with [Kiwa Italia](#).

The performance of surveillance audits is subject to the regular payment of previous activities by the Organisation. If the Organisation fails to fulfil its payment obligations, [Kiwa Italia](#) reserves the right not to carry out the planned activities and suspend or withdraw the certificate.

#### 4.3.1 Documentary assessment, including the update of clinical data

The documentary analysis is usually carried out at the same time as planned surveillance audits and is usually performed on-site or off-site, depending on scheduling needs.

The verification of documents relating to clinical data shall, where possible, be organised close to or in conjunction with the planned surveillance audit, however, it is not normally carried out at the Organisation's premises.

For class III devices and implantable devices, [Kiwa Italia](#) shall also carry out an assessment of the Periodic Safety Update Report (PSUR) in accordance with the frequencies set out by the MDR, and shall draw up a report to be uploaded to EUDAMED<sup>11</sup>; the Organisation is responsible for providing [Kiwa Italia](#) with such PSUR drawn up and updated in accordance with 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 findings resulting](#) from the documentary analysis shall be notified to the Organisation within the audit report and managed in accordance with the methods set out in paragraph 4.3.2.

Conversely, for findings resulting from the analysis of clinical data, [Kiwa Italia](#) shall send the findings management form (MOD FT 01 MED) to the [Organisation](#), both as a signed, non-editable PDF and as an editable Word file in order to enable the management of the CAP; it is specified that, for such findings, an Additional Assessment shall always be required for the approval of the CAP and subsequently for verification of the resolution of the implemented corrective actions which shall be carried out as follows:

1. in case of critical findings: within 3 months of receipt of the findings by the Organisation;
2. in case of non-critical findings: [during the subsequent annual surveillance activity](#).

[Kiwa Italia](#) may define different timeframes depending on the contents of the findings and of the actions needed for their resolution.

In all cases, if the [Organisation](#) fails to send the CAP to [Kiwa Italia](#) within the abovementioned timeframes, [Kiwa Italia](#) is entitled to suspend the certification activity.

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#### 4.3.2 On-site audits

On-site audits are always performed at the sites where activities related to products subject to certification are carried out. Moreover, such audits include the assessment of any Critical Suppliers as defined in the periodic conformity assessment programme. In defining the aspects to be verified, [Kiwa Italia](#) decides the Critical Suppliers to be audited. [Kiwa Italia](#) may decide, also based on the results of periodic audits, not to carry out the audit at a Critical Supplier where:

1. the Critical Supplier is certified by [Kiwa Italia](#) with reference to the schemes ISO 13485, Annex IX or XI of the MDR (Annex II or V of the MDD, [only in the cases of validity of the Legacy Devices transitional period and the MDR](#)

<sup>11</sup> Until the date of the complete application of EUDAMED, the [Organisation is required](#) to make the PSUR available close to the date of the surveillance audit upon request by [Kiwa Italia](#) which shall make its PSUR evaluation available to the competent Authorities, the European Commission and the Designating Authority upon request.

certification process is ongoing) or ISO 9001, for the processes/services provided to the Organisation (related to the MD to be certified);

2. the Critical Supplier is certified by another Accredited or Notified Certification Body under schemes equivalent to those referred to in the previous point and is properly monitored by the Organisation<sup>12</sup>

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 emerged in previous audits is evaluated, as well as the evaluation of the implementation and effectiveness of the corrective actions taken by the Organisation.

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

Kiwa Italia 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 Italia finds inconsistencies between the sample taken from the manufactured Legacy Devices and the specifications mentioned in the technical documentation, Kiwa Italia suspends or withdraws the relevant certificate or imposes reductions/limitations (if applicable). Additional details concerning testing activities are described in paragraph 4.4.

At the end of the audit, Kiwa Italia Audit Team provides a copy of the audit report, which shall be signed by the Organisation. The report shall be deemed confirmed if no further communications are issued to the Organisation within 60 working days.

If any NCs are identified, the Organisation shall send the CAP with the implementation timeline to Kiwa Italia Lead Auditor by using Kiwa Italia appropriate forms, within 20 working from the end of the audit. The Lead Auditor shall assess the proposed actions, accepting them or not, and shall inform the Organisation within 15 calendar days.

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

The implementation and effectiveness of corrections and corrective actions referring to minor NCs are assessed by Kiwa Italia during the subsequent periodic surveillance audit. Depending on the number and content of the identified minor NCs, an Additional Assessment may be necessary to close such findings (the related costs are borne by the Organisation), which may be performed within 6 months from the date of the NC or in conjunction with the subsequent periodic surveillance based on Kiwa Italia's decision. Kiwa Italia shall inform the Organisation accordingly.

In case of major NCs that have an impact on product safety, certification shall be suspended (or, where applicable, reduced). Moreover, for each major NC, the implementation of corrections and corrective actions shall be evaluated by means of an Additional Assessment, in accordance with the modalities established by the Lead Auditor (audits at the Organisation's premises and/or by means of documentary 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 Italia shall decide on subsequent actions. In the event of a positive outcome of the above-mentioned Additional Assessment, certification is confirmed. If the Organisation fails to implement the agreed actions for the resolution of findings within the allowed terms, certification may be withdrawn at Kiwa Italia's discretion.

It is specified that, in all cases where a CAP is present, an Additional Assessment is always needed to approve the CAP and for the verification of the resolution of the implemented corrective actions for major and minor NCs, where their number or complexity so requires as described above.

#### 4.4 Unannounced audits

Kiwa Italia 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 the European Commission Recommendation 2013/473/EU.

Kiwa Italia may increase the frequency of unannounced audits, for instance when MDs present a high potential risk and/or are often non-compliant and/or where there are specific reasons for suspicion regarding the conformity of the MDs and/or the Organisation.

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

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<sup>12</sup>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.

The Organisation also undertakes to include, in the contracts governing the relationships with its Critical Suppliers, prior authorisation for Kiwa Italia 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 for signature and visit (if legally applicable). Moreover, Critical Suppliers shall undertake to provide the Organisation, who in turn shall promptly inform Kiwa Italia, with information about the periods of the year (company closure periods, holidays, stops in production, etc.) in which they do not supply their services on behalf of the Organisation.

Kiwa Italia Audit Team presents itself at the sites where activities related to the products subject to certification are carried out, identifying itself by means of identification badges and an identification letter. The Organisation may contact Kiwa Italia offices and request a copy of the identification letter to verify its authenticity.

During an unannounced audit, the following are verified:

- a) the maintenance of conformity of the Legacy Devices subject to sampling, with regard to the approved technical documentation (assessment of the technical file) and the provisions of law.
- b) The traceability of all used components and critical materials, in particular by comparing the correspondence between the purchased materials and the outgoing finished products.
- c) The maintenance of conformity of the approved quality management system.

When carrying out unannounced audits, Kiwa Italia 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 documentation and the provisions of law, by means of tests as well.

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

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

If an external laboratory is used, samples shall be packaged and sent by the Organisation 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 documentation occur, Kiwa Italia suspends or withdraws the relevant certificate or imposes reductions/limitations (if applicable).

After the audit, the Lead Auditor provides 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, compiled by the Organisation's designated personnel and/or by its 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 duration of the unannounced audit, the report shall only be closed by the Lead Auditor after the test results and sent to the Organisation together with the test reports from the external laboratory. A non-completed copy of the report can be issued upon Organisation's request.

The results of unannounced audits are managed in accordance with the methods described in paragraph 4.3.2.

If the Organisation or its Critical Suppliers refuse to be subject to an unannounced audit or to grant access to the premises to be audited, the Organisation shall make the refusal official (on official letterhead, duly stamped and signed) and specify the reasons for which it was not possible to perform the audit. Kiwa Italia reserves the right to evaluate the actions to be taken, which may lead to the suspension or withdrawal of certification. The Organisation is promptly informed of the decisions taken.

#### 4.4.1 Sampling from the market

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

This may occur, for example, if during an unannounced audit there are no products available for sampling, or at any other stage of the certification process in the event of complaints, reports or suspected cases of product non-compliance.

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

#### 4.5 Assessment of non-significant changes

##### 4.5.1 Changes

Only non-significant changes<sup>13</sup> to certified **Legacy Devices** are permitted, **that** fall within those allowed pursuant to Article 120 (3 c, point b) of the MDR and the document MDCG 2020-3.

Therefore, if the Organisation intends to modify the **Legacy Devices**, it shall first (i) ensure that the planned changes fall within the abovementioned non-significant changes by applying Guideline MDCG 2020-3, and (ii) send an appropriate **notification** to Kiwa **Italia** including the following information in order to request Kiwa Italia to assess the admissibility of such planned changes before their implementation by the **Organisation**.

It is specified that requests for changes not notified in advance cannot be taken into consideration during the planned annual audits at the Organisation's premises.

The Organisation shall send the abovementioned notification in writing to Kiwa **Italia**, specifying the following information:

- description and clear identification of the requested change with a comparison with the current situation (including pictures, if necessary) and supporting evidence documents;
- certified device(s) to which the change refers (codes, model, etc.);
- reference technical file and relevant impact;
- reference MDD certificate number;
- rationale used to support that the change is non-significant by applying Guideline MDCG 2020-3;
- rationale used to define the non-significant change as *substantial*<sup>14</sup> or *non-substantial* in accordance with NBOG 2014-3.

Upon receipt of such notification and based on the received information and documents, Kiwa **Italia** shall evaluate the acceptability of the proposed change project and shall proceed 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 Italia** shall inform the Organisation that such planned change cannot be adopted and implemented in the **Legacy Device**;
- 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 **Italia** shall inform the **Organisation** that the planned change is feasible and specify the subsequent actions to be **taken**. In particular:
  - for *non-significant and substantial changes*, the Organisation shall not adopt such changes without a prior evaluation and approval by Kiwa **Italia**. The **Organisation, therefore** shall submit an official request for change as per paragraph 4.5.2;
  - for *non-significant and NON-substantial changes*, the **Organisation** may adopt such changes without any prior evaluation and approval by Kiwa **Italia**, which shall send a specific communication specifying the terms for verifying the implementation of such change during the subsequent 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 **Italia** before their implementation by the **Organisation**, once such changes are defined as non-significant pursuant to Article 120 (3 c, point b) of the MDR:

- changes to the **Organisation's** sites and manufacturing sites of Critical Suppliers;

<sup>13</sup> Changes that do not involve significant changes in the design and intended use.

<sup>14</sup> 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 **that require** a conformity assessment prior to the approval of the change by Kiwa **Italia**. 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".

- **critical** 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 (technologies, parameters, premises, equipment, etc.) and changes to sterilisation or special coating processes;
- changes to the **Legacy Devices, such as** operating **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 of the intended use of the **Legacy Devices** or clarifications;
- changes to the range of the **Legacy Devices**. Additional variants are acceptable, if they are included in a range already approved;
- changes to the company name and registered office of the Organisation, company changes involving the Organisation, change to the **Authorised Representative**.

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

For non-significant and substantial changes the Organisation shall fill in the information form **MOD PO 09 MED\_MDR\_AS** sent by **Kiwa Italia** to request the evaluation and approval of the change.

Based on the information reported in the form, **Kiwa Italia** prepares the economic quotation **with the same principles and methods described in § 4.1.4**.

The acceptance of the quotation by the Organisation determines the entry into force of the agreement with **Kiwa Italia** 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 Italia** 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 Italia** 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 Italia** 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 **Organisation** with the relevant reasons.

Moreover, if inconsistencies regarding statements in the information form emerge during the documentary assessment or the audit, the quotation may be subject to review by **Kiwa Italia**.

Finally, if during document analyses and/or on-site evaluations it emerges that the change significantly affects 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 Italia shall be responsible for informing the Organisation**.

#### 4.5.3 Documentary assessment of non-significant and substantial changes

The documentary assessment 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 Italia** only after receiving the Application for Changes and the approval of the review of such Application carried out by **Kiwa Italia** (see paragraph 4.5.2).

Such activity shall be planned accordance with what is established in the agreement by **Kiwa Italia**, within the certification process, and aims at verifying that the changed MD and/or the quality management system continue to comply with the applicable **MDD** requirements and the additional provisions **as per Art. 120 (3 c, point b) of the MDR**. The documentary assessment shall consist in evaluating the changed parts of the technical documentation and/or procedures of the quality management system.

After the documentary assessment is completed, Kiwa [Italia](#) sends to the [Organisation](#) 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 implementation schedule for their resolution to Kiwa [Italia](#) by using the form (MOD FT 01 MED), within 20 working days from the date of receipt of the abovementioned report by Kiwa [Italia](#); if the [Organisation](#) fails to send the CAP within the abovementioned timeframes, Kiwa [Italia](#) is entitled to suspend the ongoing certification.

It is specified that an Additional Assessment shall always be performed by Kiwa [Italia](#) to approve the CAP and subsequent such approval. Such activity shall be planned by Kiwa [Italia](#) which shall inform the [Organisation](#) 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 decision for the formal approval of the changes by [Kiwa Italia](#).

If the [Organisation](#) refuses the abovementioned Additional Assessments, Kiwa [Italia](#) 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 documentary analysis shall be completed within 1 year from the date of completion of the first analysis; beyond this time limit, Kiwa [Italia](#) 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 modalities as those described in the paragraph 4.3.2, but the evaluations shall involve the parts of the quality management system impacted by 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 [Italia](#) 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 decision, Kiwa [Italia](#) shall send to the [Organisation](#) a [Clearance Letter approving](#) the change; such letter shall not be understood as a supplement to the certificate, but represents [an additional document that amends the certificate and](#) that shall always be attached to [this](#) certificate as a proof of change approval.

In the event of an unsuccessful decision, it shall not be possible to proceed with the approval of the change; such decision shall be formally communicated to the [Organisation](#).

During the change decision process, Kiwa [Italia](#) may deem it necessary to request clarifications: from personnel who carried out the conformity assessments, [from the Organisation](#), as well as a further activities of Additional Assessments or additional data/documents.

If during the assessment and approval of changes the contract with the [Organisation](#) terminates due to any reasons, the approval of changes cannot be completed. The [Organisation](#) shall pay for the activities carried out until that moment to Kiwa [Italia](#) anyway.

Kiwa [Italia](#) 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 standard certification process, Kiwa [Italia](#) reserves the right to perform any additional assessments (on documentary 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 the *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 incidents, emergencies or malfunctions;
- in case of received reports or notices regarding non-compliant aspects related to certified **Legacy** medical **Devices**.

Kiwa **Italia** shall inform the **Organisation** 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 **Italia**, utmost attention shall be paid to their selection.

The Additional Assessments shall be charged to the **Organisation** and be performed by **Kiwa Italia** based on the prices reported in the quotation signed by the **Organisation**; 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 **Organisation** refuses – or does not allow **Kiwa Italia** to perform – the Additional Assessment and/or refuses to pay the fees and costs for such Additional Assessment to **Kiwa Italia**, **Kiwa Italia** 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.

## 5. SUSPENSION, WITHDRAWAL OR REDUCTION OF CERTIFICATION

The certification may be suspended/withdrawn/reduced for the reasons already indicated in this regulation, in the accepted quotation, in the *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 Italia** of any actions by the public authority, and/or incidents 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 Italia**.
- c. References to certification or use of **Kiwa Italia** 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 Italia** reserves the right to request to the **Organisation**:

- 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 Italia** by the **Organisation**);
- 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<sup>15</sup> on the label, or with the identification number of the NB other than **Kiwa Italia** which issued the MDD certificate<sup>16</sup> can no longer be placed on the market.

In the event of suspension/withdrawal/reduction, **Kiwa Italia** shall notify the **Organisation** in writing, identifying the MDs subject to the specific measure (which shall be limited in cases of reduction) and in the cases of suspension, by communicating the conditions that the **Organisation** 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 Italia**'s Designating Authority and the Competent Authority of the Member State in

<sup>15</sup> Ref. paragraph 6.

<sup>16</sup> In the case of a transfer of Appropriate Surveillance where **Kiwa Italia** is the incoming NB/MDR pursuant to Article 120, 3 e of the MDR.

which the [Organisation](#)'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 [Organisation](#) loses, for the duration of the suspension, its right to place on the market the MDs with CE 0476 mark, i.e. the mark of the NB other than [Kiwa Italia](#) that issued the MDD certificate, and refer to the certification and the relevant CE certificate with any means of communication; the [Organisation](#) shall also stop using all advertising material that contains relevant references and return any certification documents upon request by [Kiwa Italia](#).

The conditions for certificate reinstatement (including the necessary activities of Additional Assessments) shall be established by [Kiwa Italia](#) according to the reasons that led to the suspension and based on the duration of such suspension. Except exceptional cases (approved by [Kiwa Italia](#) or the Competent Authority), the period of suspension shall not last longer than 6 months. If the [Organisation](#) fails to implement the actions indicated by [Kiwa Italia](#) 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 [Organisation](#), immediately from 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 Italia](#) 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 Italia](#) in any case.

For [Legacy Devices](#) registered in the National Medical Devices Database of the Italian Ministry of Health ([BD/RDM](#)), in the event of a reduction of the certification, the [Organisation](#) 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 Italia](#) 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 [Organisation](#) shall use the CE marking No. 0476 by [Kiwa Italia](#) as defined in Annex XII to the Directive.

The following rules apply in addition to what is indicated in the quotation and the *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 [Legacy Devices](#) that do not comply with what is reported in the certificates, or whose certificates were withdrawn/suspended;
- the certificate has expired<sup>17</sup>;
- the certification of the [Legacy Devices](#) has been withdrawn/suspended/reduced;
- the application for a certification change of the [Legacy Devices](#) has not been approved yet or has been rejected;
- the [Organisation](#) has not implemented the changes requested by [Kiwa Italia](#).

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<sup>17</sup> The certificates no longer valid with regard to the transitional period set forth in the MDR are also included.

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

If the [Organisation](#) transfers the appropriate surveillance activities to another NB/MDR other than Kiwa [Italia](#), but continues to affix the CE No. 0476 mark on the products subject to certification, the [Organisation](#) shall continue to comply with all abovementioned rules of the correct use of the CE No. 0476 mark.

## 7. ORGANISATION'S OBLIGATIONS

### 7.1. Organisation's obligations for Annex II, V and VI to the Directive

The [Organisation](#) shall:

- Provide Kiwa [Italia](#) with all necessary information regarding the [Organisation](#), products or categories of products subject to certification and any Suppliers.
- Inform Kiwa [Italia](#) of all sites in which the Device is manufactured/designed, especially if such sites do not correspond to the [Organisation](#)'s operational sites.
- Provide Kiwa [Italia](#) with all necessary technical and quality management system documentation 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 [Italia](#) of the periods of the year in which [Organisation](#)'s activities are suspended (e.g. manufacturing of certified [Legacy Devices](#), company holiday periods, etc.).
- Maintain the MD conformity with the applicable requirements of the Directive, the provisions under Article 120 (3 d) of the MDR and the relevant national legislative provisions<sup>18</sup>.
- Fulfil the obligations imposed by the quality management system approved by Kiwa [Italia](#), 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 the 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 [Italia](#), sending information relating to changes and receiving approval from [Kiwa Italia](#) before implementing any non-significant and substantial changes (Article 120, 3 c, point b).
- Establish a procedure to manage complaints and reports received from its own customers and stakeholders that affect the conformity of the [Legacy 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 [Italia](#) 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-market clinical follow-up performed or planned in relation to the [Legacy 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 [Legacy 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.

<sup>18</sup> 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 [...]".

- Promptly inform the Competent Authorities and Kiwa [Italia](#) as soon as the Organisation becomes aware of any incidents 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 incident, 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 [Italia](#) 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 documentation proving the compliance with the essential requirements and the application of the quality management system. If the Supplier's documentation is protected by trade secrets which do not allow the Supplier to disclose them to the Organisation, an objective explanation shall be available to support it and Kiwa [Italia](#) shall evaluate such explanation with regard to the suitability of process trade secrets. However, such documentation shall be available to Kiwa [Italia](#) during the audit.

## 7.2 Additional [Organisation's](#) obligations

The [Organisation](#) shall also:

- Comply with the provisions under paragraph 3.1;
- For the transfer of the appropriate surveillance from Kiwa [Italia](#) (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 [Italia](#) to enter into it by the three parties; in the case of a transfer of appropriate surveillance from Kiwa [Italia](#) to another NB, the existing agreement between Kiwa [Italia](#) and the [Organisation](#) becomes ineffective from the effective date of such transfer established in the Transfer Agreement; the [Organisation](#) shall pay to Kiwa [Italia](#) all due amounts for the activities performed until such date.
- In any case of transfer of the appropriate surveillance – from or to Kiwa [Italia](#) – pursuant to Article 120, paragraph 3 e of the MDR, provide any document and information required by Kiwa [Italia](#) within the terms set by Kiwa [Italia](#), in order to finalise the Transfer Agreement and transfer the appropriate surveillance.
- Inform the stakeholders (e.g. competent authorities, designating authorities, NB other than Kiwa [Italia](#) 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 [Italia](#) 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 [Italia](#) of each Device with a MDD certificate issued by Kiwa [Italia](#) for which the [Organisation](#) intends to benefit from the Transitional Period (even when the [Organisation](#) 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 [Italia](#) shall be liable for the appropriate surveillance of the Device only from the first conformity assessment activity which shall be carried out by Kiwa [Italia](#) under the appropriate surveillance agreement entered into between the [Organisation](#) and Kiwa [Italia](#); therefore, the [Organisation](#) shall exonerate Kiwa [Italia](#) from any liability and also hold Kiwa [Italia](#) 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 [Legacy](#) Devices on the market that may have occurred prior to the first conformity assessment activity carried out by Kiwa [Italia](#) under the abovementioned appropriate surveillance agreement.

## 8. COMPLAINTS AND APPEALS

### 8.1 Complaints

The [Organisation](#) may file a documented complaint regarding its relationship as to certification activities with Kiwa [Italia](#).

Such complaint may arise from issues encountered during the certification process, such as delays in completing the various stages and/or incorrect conduct by personnel of Kiwa [Italia](#) which carry out conformity assessment.

Complaints shall be sent in writing (any type of support is accepted) and describe the situation complained about in detail. Kiwa [Italia](#) shall reply to confirm whether the complaint has been taken into charge or not, here the complaint does not relate to activities for which Kiwa [Italia](#) may be considered responsible.

Kiwa [Italia](#) records and examines all complaints, and informs the claimant of the actions taken within thirty days from the date of receiving the complaint.

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

[Kiwa Italia](#) 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](http://www.kiwa.it)

## 8.2 Appeals

If the claimant is not satisfied with the response, or intends to appeal against [Kiwa Italia](#)'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 Italia](#) (e.g. reporting a major non-conformity), it shall be lodged with [Kiwa Italia](#) 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.

[Kiwa Italia](#) shall provide the petitioner with a written response and notify any actions to be undertaken within 30 working days from the date of the lodged appeal.

The procedure to lodge an appeal is available on the website [www.kiwa.it](http://www.kiwa.it)

## 9. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT

[Kiwa Italia](#) 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 Italia](#) determines the withdrawal of the issued certification. In any case the Organisation shall pay to [Kiwa Italia](#) the amounts due for the services received during the notice period, as established in the latest valid quotation.

If the [Organisation](#) 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 [Organisation](#) 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 Italia](#) 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 Italia](#) 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 [Organisation](#). The new version of this regulation shall be available on [Kiwa Italia](#) website ([www.kiwa.it](http://www.kiwa.it)).

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 Italia](#).

The termination shall become effective from the last working day of the month in which the [Organisation](#)'s notice is received.