REGULATION FOR THE CERTIFICATION OF MEDICAL DEVICES UNDER REGULATION (EU) 2017/745

Kiwa Cermet Italia S.p.A. - Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
Sede legale: Via Cadriano 23, 40057 - Granarolo dell'Emilia (BO) - Iscritta al Registro della Camera di Commercio di Bologna con il numero di iscrizione e C.F.03502820370, REA: BO-295316, P.IVA 00627711203 - Capitale Sociale: € 1.000.000,00 i.v.
Tel. +39.051.4593.111 - Fax +39.051.763.382 – it.info@kiwa.com – PEC: kiwa@pec.kiwaitalia.com - www.kiwa.it

INDEX

STATUS OF REVISIONS		
Rev.	SUMMARY OF CHANGES	DATE
7 bis	Alignment with a new amendment to Annex VII of the MDR	2026-05-11
7	The revision was necessary to correct an editorial error in rev. 5 of the English translation, in § 11, regarding the notice period for withdrawal from the contract. Other minor corrections of typographical errors. The Italian version in revision 6 remains in force.	2026-03-06
VERIFICATION	Compliance Manager Dr. Alessandra Zazzera	
APPROVAL	Compliance and Legal Affairs Director Eng. Maria Anzilotta	

1. SCOPE AND FIELD OF APPLICATION

This Regulation defines the rights and duties, as well as the operational methodology governing the relationships between Kiwa Cermet Italia S.p.A. (hereinafter referred to as "Kiwa Italia") and the Organisation[1], in the implementation of the different conformity assessment procedures provided for in Regulation (EU) 2017/745 and subsequent amendments (hereinafter also referred to as MDR) for:

- medical devices for human use and their accessories[2] (hereinafter also referred to as "MD");
- products without an intended medical purpose and their accessories, as indicated in Annex XVI of the MDR, starting from the date of application of the Common Specifications adopted pursuant to Art. 9 of the MDR (hereinafter also referred to as "MD");
- systems or procedure packs as referred to in Art. 22 (3) of the MDR;

for which Kiwa Italia is authorised to operate as Notified Body – 0476 (hereinafter also referred to as "NB") pursuant to the designation issued by the Italian Ministry of Health as Designating Authority[3]. The types of MD for which Kiwa Italia is authorised to operate are reported in the EU NANDO Information System.

This Regulation also applies to the quality management system (hereinafter also referred to as "QMS") referred to in Article 16 (3) of the MDR applicable to the distributor or importer carrying out any of the activities referred to in Article 16 (2), letters (a) and (b) of the MDR.

The conformity assessment activities described in this Regulation are carried out in accordance with the harmonised standards, the Common Specifications and the European guidelines applicable to the medical sector, in force at the time the activities are performed.

The requirements set out in this Regulation form an integral part of the contract entered into with Kiwa Italia, which includes the economic quotation signed by the Organisation, the *Kiwa Regulations for Certification*, and the *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders* (hereinafter referred to as "*General Terms and Conditions*").

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

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

2. TERMS AND DEFINITIONS

For the purposes of interpreting this Regulation, the definitions set out in Article 2 and in Annex VIII, Chapters I and II of the MDR shall apply and, in addition, the following shall be taken as reference:

- **Supplier**[4]: natural person or legal entity providing a product or a service, as defined by ISO 9000 in its current version.
- **Critical supplier**: the Supplier as defined above, who provides products or services that significantly affect the safety and performance of the MD, whose failure to meet the applicable requirements may result in an unacceptable risk for the patient, the user or other involved subjects, or may cause a significant deterioration of the performance themselves (e.g. design, custom components, special processes, raw materials, semi-finished products, etc.) or compromise compliance with regulatory requirements. *Note: For the purposes of this document, the term critical supplier is considered synonymous with the term "relevant supplier" as reported in the MDR. The definition of critical supplier also includes the critical sub-suppliers of the supplier referred to in Annex VII, Point 4.5.2 (a), indent 2 and in Annex IX, Point 2.3, second paragraph, for which the NB is required to carry out audits, where applicable.*
- **Critical Component**: a component of an MD is defined as critical when its failure could lead to a hazardous situation, as a result of a risk analysis or a usability study.

[1] The term *Organisation* refers to any economic operator, as defined in Article 2, point 35 of Regulation (EU) 2017/745, to which the aforementioned Regulation applies.
[2] For the definition of 'medical device' and other sector-specific terms, reference is made to Article 2 of Regulation (EU) 2017/745.
[3] In accordance with the reference legislation "Designating Authority" means the authority or authorities designated by a Member State to assess, designate, notify and monitor Notified Bodies: https://ec.europa.eu/growth/tools-databases/nando
[4] This definition also includes the terms 'Subcontractor' and 'Sub-supplier' as used in the MDR.

- **Critical (Ingredient) Material**: any substance or combination of substances with defined chemical and physical properties, whose variation, degradation or substitution may affect the quality, safety and performance of the device, for example the benefit-risk ratio.
- **Calendar Days**: all consecutive days defined by the calendar.
- **Working Days**: calendar days excluding Saturdays, Sundays and public holidays according to the Italian National Calendar.
- **Substantial change**: as defined in Annex IX, Point 2 (4) of the MDR and requiring prior approval; it refers to changes considered critical according to the risk management system approved by the manufacturer, concerning:

  1. the approved QMS, including:

     - changes to approved processes and procedures[5], including critical procedures[6] and the procedure for the management of changes;

     - changes to the scope of the QMS that affect the contents of the EU Certificate and/or the audit programme established by Kiwa Italia, and in particular with regard to manufacturer's sites, organisational chart, critical suppliers, activities (e.g. design, development, production, after-sales assistance and installation), technologies, procedures[7] and critical processes, including sterilisation.

  2. the range of devices included in the EU Certificate of the QMS.
- **Modification of the approved device subject to prior approval**: as defined in Points 4.10, 5.2 (f), 5.3.2 and 5.4 (b) of Annex IX of the MDR; these refer to modifications relating to approved devices covered by an EU Technical Documentation Assessment Certificate, where such changes may affect the safety and/or performance or the conditions prescribed for use.
- **Administrative change that requires prior approval:** refers to changes affecting the content of the certificate that shall be notified to and approved by Kiwa Italia before their implementation.
- **Supplementary assessment**: assessment not provided in the standard process, subject to additional charges for the Organisation, which becomes necessary for the reasons indicated in this Regulation (or in documents referred to therein).

3. GENERAL PRINCIPLES AND GUARANTEES FOR THE ORGANISATION

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

a) non-discrimination: access to certification services is granted to any Organisation to which the MDR applies and which requires the involvement of a NB, in accordance with this Regulation, without any discriminatory condition of a commercial or financial nature or related to membership of particular associations.

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

- punctual implementation of formalised rules and procedures in use by all personnel involved in certification services and periodic consultation with appropriate stakeholders in certification;
- performance of certification activities assigned to personnel who do not have any interest in the Organisation subject to certification and who are required to observe the rules of conduct, impartiality and independence established by Kiwa Italia; in this respect, Kiwa Italia agrees to accept any duly justified reports from the Organisation, within 3 Working Days from the notification of the names, concerning the existence of incompatibility of the assigned task that could compromise impartiality or independence of judgement;
- clear separation between the personnel performing conformity assessment activities and the personnel involved in the final review and certification decision;

[5] Those provided for in Article 10(9) of the MDR.
[6] See Annex IX, Section 2.2(b), indent 1, and Article 10(9) of the MDR: regulatory compliance strategy, including compliance with conformity assessment procedures and procedures for managing changes to devices covered by the system.
[7] See MDR Annex VII, Section 4.5.6, i.e. the procedures referred to in Sections 5 and 6 of Annex IX and in Section 16 of Annex XI.

- provision of only those services compatible with the activities of the NB (no consulting services are provided in relation to the design, production, marketing or maintenance of MDs or of the processes subject to assessment);

c) prompt management of complaints and appeals, as defined in § 10 of this Regulation;

d) confidentiality: in addition to what is regulated in the *General Terms and Conditions* and in the *Kiwa Regulations for Certificatio*n, all Customer data and information are handled with the utmost confidentiality, unless otherwise required by legal provisions, including the MDR. Furthermore, Kiwa Italia requires all personnel, including personnel performing conformity assessment activities, to sign a confidentiality commitment as well as a document in which they undertake to process any data they access in compliance with applicable Privacy legislation. A similar commitment to confidentiality is ensured by Control Bodies, the European Commission, and Competent and Designating Authorities, as well as other third parties pursuant to legal provisions, to whom Kiwa Italia must grant access to Customer data. Information exchanged confidentially among these parties shall not be disclosed without prior agreement of the authority that transmitted them. Confidentiality obligations shall not prejudice the rights and obligations of the Commission, the Member States and the NB regarding the exchange of information and the dissemination of safety notices, nor the obligations of the persons concerned to provide information in accordance with criminal law. The European Commission and the Member States may exchange confidential information with regulatory authorities of non-EU countries with which they have concluded bilateral or multilateral confidentiality agreements. Kiwa Italia shall process personal data made available by the Organisation as an independent data controller, for the purposes indicated in the privacy policy provided to the Organisation;

e) designation as Notified Body: Kiwa Italia undertakes to inform the Organisation of any renunciation, reduction, suspension or withdrawal of the ministerial notification; in such cases, Kiwa Italia shall not be in any way liable for any damage caused to the Organisation by the renunciation, reduction, suspension or withdrawal of the notification; in such cases, the Organisation has the right to withdraw from the contractual relationship with Kiwa Italia without prior notice and without additional charges. Where the designation has been suspended, limited or withdrawn, Kiwa Italia shall follow the instructions of the responsible authority and inform the Organisations concerned no later than 10 Calendar Days from the decision. Where Kiwa Italia decides to cease conformity assessment activities, it shall inform the authority responsible for NB and the manufacturers concerned as soon as possible and, where the cessation is planned, one year before the termination of the activities. The certificate issued to the Organisation may remain valid (at the sole discretion of Kiwa Italia) for a temporary period of nine months after Kiwa Italia ceases its activities, provided that another NB has confirmed in writing that it will assume responsibility for the devices covered by the certificate.

Kiwa Italia also undertakes to:

- provide, upon request, a list of any subsidiaries used in the certification activities covered by this Regulation and, in the event of outsourced activities, undertakes to inform the Organisation of the subcontractors used;
- carry out structured and organised discussion sessions (hereinafter “Structured Dialogue”) aimed at clarifying requirements, interpretations and expectations relating to the conformity assessment process, in order to optimise the efficiency and predictability of the process, without compromising the requirements of independence, objectivity and impartiality. Structured Dialogues may take place both in the preliminary phases and in the phases following the submission of the Application for certification and are focused on providing explanations of what must be fulfilled within the conformity assessment process. The topics that may be discussed are those specified in MDCG 2019-6, §§ I.6.2, I.6.3.

4. ACCESS REQUIREMENTS FOR CERTIFICATION

4.1 General Obligations of the Organisation

In addition to what is provided for in *the General Terms and Conditions* and in *the Kiwa Regulations for Certification*, at the Application for certification stage, the Organisation shall commit to comply with the following requirements:

- accept the conditions set out in this Regulation, which is also available on the website (www.kiwa.it). In any case, Organisations intending to conclude a contract with Kiwa Italia may request an electronic copy. Kiwa Italia shall communicate any subsequent amendments to the contractual documents; however, it is the responsibility of the Organisation to always have the updated version of such documents by downloading them from the website www.kiwa.it;
- establish and maintain a QMS including the selection and control of suppliers and, among them, identify those classified as Critical suppliers;

- comply with and ensure compliance, by all economic operators involved in the life cycle of the MD subject to certification, with all applicable obligations laid down in Regulation (EU) 2017/745; therefore, for illustrative purposes only and not exhaustive, by entering into specific contractual agreements with authorised representatives, importers, exporters, distributors as well as Critical suppliers. In particular, with Critical suppliers, a contractual requirement shall be established guaranteeing access for Kiwa Italia to all supplier's sites and documents (including downstream in the supply chain where applicable, by entering into an agreement with the sub-supplier) where the MD subject to certification are produced or processed, both during certification, periodic and renewal audits, as well as during unannounced audits; otherwise, Kiwa Italia may refuse the certification Application or refuse to proceed with it. The supplier shall also provide the Organisation with all technical documentation and QMS documentation necessary to demonstrate compliance with safety and performance requirements and with the application of the QMS;
- enter into and maintain in force, proportionate to the risk class, the type of device and the size of the enterprise, an adequate insurance policy covering potential liability pursuant to Directive 85/374/EEC in order to demonstrate compliance with Article 10 of Regulation (EU) 2017/745. The maintenance of such insurance policy shall be verified by Kiwa Italia during the review of the certification Quotation and during the audits within the certification cycle, by checking the valid Professional / Product Liability insurance certificate and the related proof of payment;
- retain the technical documentation, the EU Declaration of Conformity and, where applicable, a copy of the EU Certificate issued pursuant to Article 56, including any amendments and supplements, for a period of at least 10 years (15 years for implantable devices) from the placing on the market of the last device covered by the EU Declaration of Conformity;
- ensure that the MD has been designed and manufactured in compliance with the MDR requirements, and in particular with the General Safety and Performance Requirements set out in Annex I of Regulation (EU) 2017/745, and maintain the conformity of the MD throughout its life cycle. Furthermore, establish, document, implement, maintain, update and continuously improve a QMS related to the MD that ensures compliance with this Regulation in the most effective way and in a manner proportionate to the risk class and the type of device;
- have at least one person responsible for regulatory compliance with the necessary expertise in the field of medical devices in accordance with Article 15 of the MDR;
- provide Kiwa Italia with all necessary information regarding the Organisation, the MDs or categories of MD subject to certification and any suppliers to whom outsourced processes are entrusted, identifying the Critical suppliers, including all information related to obligations concerning the UDI system referred to in Articles 27, 29 and 31 of Regulation (EU) 2017/745;
- inform Kiwa Italia of all locations where the device is designed and manufactured, particularly where such locations do not correspond to the Organisation's operational site;
- at the stage of acceptance of the Quotation, expressly declare that no Application for certification has been submitted for the same device to another NB; or provide information on any previous Applications for certification relating to the device that have been refused or withdrawn;
- ensure that Kiwa Italia personnel are granted all necessary facilities and access to documents required to carry out conformity assessment activities, including access, during audits, to all areas subject to assessment;
- appoint its own Representative as the main contact person for the conformity assessment team and ensure that any consultants present during the audit act solely as observers;
- be responsible for compliance with the applicable requirements set out by the occupational health and safety regulations. The Organisation undertakes to provide Kiwa Italia with complete and detailed information on the specific risks present in the environment where Kiwa Italia personnel will operate and the necessary PPE for carrying out the assignment, informing Kiwa Italia personnel on their proper use. In this regard, the Organisation shall provide the personnel appointed by Kiwa Italia with company documentation relating to occupational health and safety (Risk Assessment Document, safety plan, procedures, etc.), limited to aspects of specific interest. Should injuries occur or illnesses be contracted due to such omissions, no charges may be made against Kiwa Italia for any reason;
- personal data protection: the Organisation shall in any case remain responsible for the lawfulness, fairness and compliance of processing activities carried out within its operations, including those subject to verification for certification purposes. In particular, the Organisation undertakes to:

- ensure appropriate information to its employees, collaborators and, where applicable, third parties, regarding audit activities and any consultation of personal data within certification activities, making available the Kiwa Italia privacy notice on the Processing of Personal Data in accordance with applicable data protection legislation;
- limit the communication of personal data to what is strictly necessary for conformity assessment purposes, favouring, where possible, evidence not involving personal data processing;
- mask, anonymise or pseudonymise non-relevant personal data, including, by way of example and not limited to, special categories of data pursuant to Article 9 of Regulation (EU) 2016/679 (GDPR), such as data relating to health, trade union membership or religious beliefs of personnel, collaborators or third parties, as well as data concerning criminal convictions and offences pursuant to Article 10 GDPR;
- ensure that any personal data communicated to Kiwa Italia are collected and processed lawfully, fairly and in compliance with applicable data protection legislation.

Where, due to specific certification scheme requirements or applicable legal obligations, it is nevertheless necessary to allow access to evidence containing special or judicial personal data, the Organisation shall ensure that such access complies with the principles of necessity and proportionality, is limited to what is strictly necessary and, where possible, takes place in a controlled manner, preferably on-site and without the possibility of duplication or acquisition of the data by the Audit Team. It is understood that Kiwa Italia does not require, nor is it required to process, personal data exceeding the purposes of certification and shall not be held liable for any improper or non-compliant transmission of personal data by the Organisation in breach of the principles of lawfulness, data minimisation, and relevance of processing. The Organisation undertakes to indemnify and hold harmless Kiwa Italia from any claim, damage or sanction arising from personal data processing carried out in breach of applicable legislation or from improper communication of personal data within certification activities;

- provide Kiwa with all technical, insurance and quality system documentation, both at the initial stage and at any other stage of the certification process;
- prepare all documentation subject to assessment by Kiwa and related correspondence with Kiwa in Italian or English. No other languages shall be accepted. For English or bilingual documentation, in case of discrepancies between the Italian and English versions, the Italian version shall always prevail. Documentation shall be complete with dates and signatures, in searchable but non-editable PDF format. Any modification to document content (words/phrases, additions and deletions) submitted to Kiwa following requests or resolution of findings and/or non-conformities shall be identified both through subsequent revisions and through methods allowing clear visualisation of changes, ensuring immediate traceability compared to the previous revision. A summary table describing the changes shall also be provided. These good practices for change management shall be formalised within the Organisation's quality management system;
- maintain, within the technical documentation, an updated list of all UDI-DI assigned to the MDs subject to certification;
- establish and implement a procedure for managing modifications affecting products subject to certification or the approved quality management system, including classification of changes, their management within the quality system, timely communication to Kiwa Italia of changes subject to notification, including relevant information regarding changes, and obtaining prior approval from Kiwa Italia before implementation (ref. § 5.5);
- ensure the registration, reporting and information procedures required by the MDR (Articles 10, 10bis, 29, 30, 31, 73, 87, 88, 92) and by the National Competent Authority;
- comply with the obligations arising from the quality management system approved by Kiwa Italia and ensure its proper and effective functioning throughout the life cycle of the MDs subject to certification. These obligations also include the systematic updating of documentation in line with regulatory updates, guidelines and the state of the art of the relevant sector;
- inform, without delay, the Competent Authorities and Kiwa as soon as it becomes aware of incidents or any potential serious risks associated with MDs made available within the territories of the European Union, as provided for in Articles 87 and 88 of Regulation (EU) 2017/745; furthermore in the event of a serious incident, carry out all activities required under Article 89 of Regulation (EU) 2017/745;
- maintain an updated, approved and signed list of codes of all devices subject to certification and provide it to Kiwa in a controlled manner;

- maintain the above obligations in case of modifications to certified products or for any extensions to new products subject to certification;
- accept, without additional charges, the possible presence of personnel of the supervisory body/Competent Authority acting as Observers, which shall be notified by Kiwa with a clear indication of their roles. Their presence is intended to verify that the assessment methods applied by Kiwa comply with the requirements for notification.

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

The Organisation must undertake to comply with the following requirements:

- Undergo conformity assessment activities, according to the selected Annex, before placing the MD on the market and before putting it into service.
- Plan, continuously conduct and document a clinical evaluation and a post-market clinical follow-up (PMCF) in accordance with Annex XIV of Regulation (EU) 2017/745, the relevant guidelines and Common Specifications published by the European Commission.
- Where applicable, carry out clinical investigations in accordance with Annex XV of Regulation (EU) 2017/745 and the relevant guidelines and Common Specifications published by the European Commission.
- For all MDs: prepare technical documentation in accordance with the selected Conformity Annex.
- For class IIa, IIb and III MDs: draft and maintain an updated periodic safety update report ("PSUR") as provided for in Article 86 of Regulation (EU) 2017/745.
- For class Is, Im and I reusable surgical instruments MDs: draft and maintain an updated post-market surveillance report (PSR) as provided for in Article 85 of Regulation (EU) 2017/745.
- For implantable MDs and for class III MDs: draw up the summary of safety and clinical performance as provided for in Article 32 of Regulation (EU) 2017/745.
- Commit to keeping the following available to the Competent Authorities and Kiwa for a period of at least ten (10) years and, in the case of implantable devices, at least fifteen (15) years from the date of placing the last device on the market:
  a) the EU Declaration of Conformity drawn up in accordance with Annex IV of Regulation (EU) 2017/745;
  b) the documentation referred to in Point 2.1, fifth indent, of Annex IX of Regulation (EU) 2017/745;
  c) the information on changes referred to in Point 2.4 of Annex IX of Regulation (EU) 2017/745;
  d) Kiwa decisions and reports referred to in Annex IX of Regulation (EU) 2017/745.

In addition, for Annex IX only:

  e) the EU Technical Documentation Assessment Certificate and the EU Quality Management System Certificate;
  f) the data and records resulting from the procedures referred to in Point 2.2, second paragraph, letter (c), of Annex IX of Regulation (EU) 2017/745;
  g) the documentation referred to in Point 4.2 of Annex IX of Regulation (EU) 2017/745.

In addition, for Annex XI only: the EU Type Examination Certificate referred to in Annex X (if applicable) and the EU Quality Assurance Certificate.

4.3 Description and Classification of results of conformity assessment activities

The results of the document analysis and of the Stage 1 audit are expressed as follows:

Critical finding: failure to comply with a requirement for certification[8] identified in the technical documentation and/or in the Quality Management System documentation relating to the MD subject to certification, which affects the ability of the product or of the related Quality Management System to achieve the expected results and therefore jeopardises the safety, the essential performance, the technical characteristics or the functionality of the product.

[8] Refers to a regulatory or legislative requirement, relating to the Organisation's documentation approved by Kiwa Italia or to a contractual requirement of Kiwa Italia.

Non-critical finding: failure to comply with, or partial fulfilment of, a requirement for certification which, although requiring correction, does not affect the ability of the product or of the related Quality Management System to achieve the expected results and therefore does not fall under the category of Critical findings.

The results of the other audits are expressed in terms of:

Major non-conformity (NC): non-fulfilment of a requirement for certification which affects the ability of the product or of the related Quality Management System to achieve the expected results and therefore compromises the safety, the essential performance, the technical characteristics or the functionality of the product. It may concern:

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

Minor non-conformity (NC): non-fulfilment or partial fulfilment of a requirement for certification which, although requiring correction, does not affect the ability of the product or of the related Quality Management System to achieve the expected results and therefore does not fall under the category of Major non-conformities described above.

Multiple Minor non-conformities relating to the same requirement, depending on their content and the overall result of the audit, may lead to the issuance of a Major non-conformity.

Minor non-conformities not resolved and/or not addressed by the Organisation may lead to the issuance of a Major non-conformity.

Opportunity for improvement: any aspect not falling within the definitions of NC, representing a potential improvement of the management system or of the product subject to certification.

5. REQUIREMENTS OF THE CONFORMITY ASSESSMENT PROCESS

5.1 General Requirements

5.1.1 Presumption of Conformity

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

Medical devices compliant with the relevant harmonised standards (including the monographs of the European Pharmacopoeia and the Common Specifications), or with relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, shall be considered in conformity with the provisions of Regulation (EU) 2017/745. This requirement also applies to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up (PMCF).

Kiwa shall operate in compliance with Regulation (EU) 2017/745, the relevant national legislative provisions[9] and all the guidance documents indicated above and applicable to the medical device sector.

5.1.2 Qualification and Classification of the MD

The Organisation intending to use Kiwa Italia for CE marking of its MDs is responsible for the specific intended purpose assigned to each device and for its qualification as an MD in accordance with Article 2 (1) and (2), and its classification as set out in Article 51 and Annex VIII of Regulation (EU) 2017/745.

Kiwa, during the review of the Application for certification, shall verify, for approval, the qualification and classification assigned by the Organisation.

In the event of disagreement between the Organisation and Kiwa Italia regarding the application of the classification rules (or regarding the qualification as an MD), Kiwa Italia shall inform the Organisation and shall subsequently submit both its own position and that of the Organisation to the Competent Authority where the Organisation has its registered office, which shall resolve the dispute in accordance with Article 51 (2) of the MDR. Where the Organisation does not have its registered office within the European Union, the matter shall be submitted to the Competent Authority of the Member State in which the Authorised Representative is established. If the Organisation is established in a Member State other than Italy, the Competent Authority of the Organisation's Member State shall adopt a decision after

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

consulting the Italian Competent Authority. Where the dispute cannot be resolved by the consulted Competent Authority, it shall contact the other Competent Authorities by activating the Helsinki Procedure.

In such cases, the review of the Application or the conformity assessment shall not proceed until the reply from the Competent Authority has been received.

5.1.3 Certification Service

The certification path followed by Kiwa for the purposes of CE marking and its maintenance is defined by the provisions set out in the applicable Annexes of Regulation (EU) 2017/745, to which reference shall be made, with the issuance of the following certificates depending on the risk class of the devices:

- EU Technical Documentation Assessment Certificate, pursuant to Annex IX (Chapter II);
- EU Quality Management System Certificate, pursuant to Annex IX (Chapters I and III);
- EU Quality Assurance Certificate, pursuant to Annex XI (Part A);

(hereinafter "Certification(s)" or "Certificate(s)").

For device groups without an intended medical purpose listed in Annex XVI, Kiwa Italia shall also perform conformity assessment activities in accordance with the relevant Common Specifications applicable to each group, with reference to risk management and clinical evaluation, and shall take into account the state of the art of analogous medical devices. In the case of a device having both a medical intended purpose and a non-medical intended purpose, Kiwa Italia shall carry out conformity assessment activities by verifying compliance with both the General Safety and Performance Requirements set out in Annex I of the MDR and the requirements established by the additional Common Specifications for that category of MD.

For the Quality Management System referred to in Article 16 (3) of the MDR, applicable to the distributor or importer carrying out any of the activities referred to in Article 16 (2), letters (a) and (b) of the MDR, Kiwa Italia shall carry out a conformity assessment process dedicated to the specific activities provided for by the scopes referred to in Point 2, letters (a) and (b) of Article 16 and shall issue a specific certificate.

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

Each Certificate is issued exclusively to the applicant Organisation, refers to a single conformity assessment procedure and is drafted in a bilingual form, in Italian and English.

The Certification issued by Kiwa Italia has a maximum validity of five (5) years; upon request of the Organisation, it may be renewed for further periods, each up to five (5) years, in accordance with the Certification renewal procedure. Extensions and/or modifications within the 5-year validity period do not extend the validity of the issued Certification.

Kiwa Italia, during the review of the Application for certification, shall verify the correctness of the conformity assessment process requested by the Organisation.

5.1.4 Conformity assessment activities

The following rules apply:

- The language of the audit shall be Italian or English; in the case of other languages, the Organisation shall ensure, at its own expense, the continuous presence of qualified translators to support the audit team.
- At the end of each audit, the conformity assessment Team meets to evaluate the recorded evidence, classify them and draft the report.

a) During the final audit meeting, the conformity assessment Team presents to Management the results of the Audit and the conclusions regarding compliance of the applied Management System, indicating any Non-conformities identified.

b) At the end of all audit activities, the Lead Auditor issues a report describing the results of the Audit.

c) In the event of recording of Non-conformities (NC) following an audit, the Organisation shall define and implement appropriate treatments to resolve the NC, carry out an analysis of the causes that generated the NC and establish the related corrective actions necessary to eliminate the identified causes, with a clearly defined process planned in terms of methods and implementation timelines. The Organisation shall communicate such action plan to Kiwa within a defined timeframe, as specified in the following paragraphs.

d) Any differences of opinion between the audit Team and the Organisation regarding the audit findings or conclusions shall be discussed and, where possible, resolved. In the case of unresolved differences of opinion, the Organisation may express reservations regarding the results of the Audit.

e) Opportunities for improvement shall be analysed by the Organisation, which may decide whether to define subsequent actions for their implementation or not. Where the Organisation decides not to act upon an opportunity for improvement, it shall in any case record the analysis carried out and the reasons for non-implementation; in such cases, Kiwa reserves the right to further investigate the reported aspect.

f) All conformity assessment reports and the results of tests carried out during the certification process shall be made available to the Competent Authorities and other interested parties, as provided for in Annex XII of Regulation 745, informing the Organisation.

5.1.5 Specific additional procedures

For certain types of MDs, MDR provides for consultations with the Competent Authorities or the expert panel referred to in Article 106 (hereinafter also referred to as "Expert Panel"), at specific stages of the process described below. Depending on the opinion expressed, Kiwa Italia shall evaluate the consequent actions, including limitations or specific conditions (see § 5.9).

The scientific opinion resulting from the consultations carried out shall form part of the technical documentation of the MD.

a) For implantable Class III devices and active Class IIb devices intended to administer and/or remove a medicinal product to or from the human body, pursuant to Annex VII, Point 6.4 (Rule 12) of the MDR, Kiwa carries out the evaluation of the clinical data reported in the clinical evaluation report prepared by the Organisation and produces an assessment report, which is transmitted to the European Commission in order to initiate the Clinical Evaluation Consultation Procedure (CECP). The Commission, in turn, transmits it to the Expert Panel referred to in Article 106 of the MDR. Without prejudice to cases where such consultation is not deemed necessary pursuant to Article 54 (2) of the MDR, Kiwa shall not proceed with the certification process until the Expert Panel provides a scientific opinion on the relevance of the clinical data and on the Kiwa Italia assessment report, in particular with regard to the determination of the benefit-risk ratio, the consistency of such evidence with the medical indications and the PMCF plan. Only where, after 21 Calendar Days from the submission of the documentation, Kiwa Italia is informed that the Expert Panel will not provide any opinion, or where 60 Calendar Days have elapsed since submission of the documentation without any opinion being received from the Expert Panel, Kiwa Italia shall proceed with the certification activities.

b) For devices incorporating a substance which, if used separately, may be considered a medicinal product pursuant to Article 1, Point 2 of Directive 2001/83/EC and which has an ancillary action to that of the device, Kiwa shall assess the Organisation's documentation to verify the quality, safety and usefulness of the substance contained in the MD, in analogy with the methods set out in Annex I of Directive 2001/82/EC, as well as the benefits and risks arising from the incorporation of the substance into the device; the results of the analysis shall be reported by Kiwa on the specific forms of the Competent Authority and transmitted thereto, which shall be selected, in agreement with the Organisation, among those designated by the Member States in accordance with Directive 2001/83/EC. Kiwa Italia shall not proceed with the certification process until the Competent Authority has issued a favourable opinion. In the case of a negative opinion, the Certification cannot be issued.

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

d) For devices manufactured using cells or tissues of animal origin rendered non-viable, or with products derived from animal tissues rendered non-viable (pursuant to Regulation 745, Article 52, paragraph 10), the Organisation shall apply the additional provisions set out in Regulation (EU) 722/2012. Furthermore, before proceeding with the conclusion of the certification process, Kiwa Italia shall submit the results of the document assessment to the Competent Authorities and take into account any observations received.

In the event of a negative opinion from the Competent Authority, the costs of any conformity assessment activities already carried out by Kiwa Italia (as described in the following paragraphs from 4.3 to 4.4) shall be borne by the Organisation.

5.2 Activation of the certification service

5.2.1 Activities prior to the submission of the Application for certification

In order to access certification services for medical devices, the Organisation shall complete *the preliminary information form for certification of medical devices Regulation (EU) 2017/745*, hereinafter also referred to as MOD PO 09 MED_MDR, which is provided upon request by the sales function of Kiwa Italia or may be completed directly on the Kiwa Italia website.

It is specified that, based on the MOD PO 09 MED_MDR, the Organisation is also required to submit to Kiwa Italia a formal declaration issued and signed by its Legal Representative, under its own responsibility and on behalf of the Organisation, stating whether it qualifies as a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC. Such declaration shall also confirm that it is provided on the basis of the number of employees, staff headcount, annual turnover, financial statements and other applicable criteria set out in the aforementioned Recommendation 2003/361/EC. It is specified that, for conformity assessment activities relating to changes or modifications referred to in Annex VII, Point 4.9 of *Regulation (EU) 2017/745, as well as* for recertification activities referred to in Annex VII, Point 4.10 of *Regulation (EU) 2017/745*, it is sufficient for the Legal Representative of the Organisation to supplement the previously submitted declaration, confirming whether (i) changes have occurred compared to the information previously provided and whether, consequently, (ii) the classification of the Organisation under Recommendation 2003/361/EC is confirmed.

For Class III and IIb implantable MDs, Kiwa Italia shall accept a conformity assessment request only in accordance with Annex IX and, in addition, for Class III MDs, with the exception of custom-made implantable devices, and Class IIb MDs referred to in Article 52 § 4 second paragraph[10], a specific request for conformity assessment of the technical documentation referred to in Chapter II of Annex IX shall be submitted for each MD to be certified. This request shall contain a description of the design, manufacture and performance of the MD.

The MOD PO 09 MED_MDR form shall be duly completed and signed in all its parts by the Organisation and shall be sent to Kiwa Italia both in non-editable PDF format and in XLS format. Together with the MOD PO 09 MED_MDR form, the required annexes shall also be submitted. Where the Organisation is established outside the European Union, the request may also be submitted by its Authorised Representative (EU Authorised Representative).

If the Organisation encounters difficulties or doubts in completing the MOD PO 09 MED_MDR form or requires clarification on the certification process, it may request a Structured Dialogue by contacting directly the sales function of Kiwa Italia.

5.2.2 Review of preliminary information and preparation of the Quotation

Based on the analysis of the preliminary information reported in the MOD PO 09 MED-MDR, Kiwa Italia prepares the Quotation, containing the financial proposal for CE marking certification, the description of the service offered, including all information relating to the conformity assessment activities to be carried out, including the related prices, determined in accordance with the applicable rates, and the estimated maximum timeframes for their completion[11].

Should inconsistencies arise in the subsequent phases of the certification process with respect to the information declared in the MOD PO 09 MED-MDR, the Quotation may be subject to revision by Kiwa Italia.

Where, based on the information contained in the MOD PO 09 MED-MDR, aspects emerge for which Kiwa Italia cannot guarantee the capability to perform the certification activity, Kiwa Italia shall inform the Organisation of the impossibility to issue the Quotation, providing the related reasons.

It is specified that, for Applications for certification submitted from 25 February 2027, as well as for recertification Applications submitted from 25 November 2027, Kiwa Italia — regardless of any contrary provisions that may be contained in the "General Terms and Conditions of Kiwa Cermet Italia for the performance of orders" applicable to the relevant contract to be entered into with the Organisation and unless shorter timeframes are agreed in the Quotation — shall fully apply the maximum timeframes provided for the phases of conformity assessment (i.e. review of the Application, Quality Management System audit, technical documentation assessment, final review and certification decision, as well as any additional activities relating to the assessment of substantial change and the issuance of the

[10] Implantable Class IIb devices such as sutures, staples, dental filling materials, orthodontic appliances, dental crowns, screws, wedges, plates and prostheses, wires, nails, clips and connectors, as well as those belonging to the list of devices considered as WET (Well Established Technology), are exempt.

[11] These maximum timeframes apply to the conformity assessment procedures for which an Application has been submitted from 25 February 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.

related certificate supplement), as well as the management of interruptions, as provided for in Implementing Regulation (EU) 2026/977.

5.2.3 Submission of the Application for certification

The Quotation duly signed by the Legal Representative of the Organisation[12] (or by a legally authorised person) constitutes the formal Application for certification, as defined in Annex VII of the MDR, Point 4.3, first paragraph, hereinafter also referred to as the "Application".

The submission of the Application entails the sending by the Organisation of all technical documentation and QMS documentation referred to in the Annex selected for the conformity assessment, as well as the valid Professional/Product Liability insurance certificate, together with the relevant proof of payment.

Once Kiwa Italia has received the Application together with the above-mentioned documents, including the MOD PO 09 MED_MDR, it shall confirm in writing whether it is complete or whether additional information is required. Any such request shall be limited to the information necessary to complete this phase.

It is specified that the submission of the Application — together with the above-mentioned documentation — to Kiwa Italia (i) shall not give rise to any contractual obligation between Kiwa Italia and the Organisation; and (ii) shall constitute a proposal by the Organisation to assign the certification activities to Kiwa Italia.

5.2.4 Review of the Application for certification and finalisation of the contract

Kiwa Italia performs a review of the Application as defined in Point 4.3, third paragraph of Annex VII of the MDR, verifying that:

- the required data and documents have been provided completely in accordance with the requirements set out in the selected conformity assessment Annex, including the QMS documentation and the technical documentation;
- the selected conformity assessment Annex, the classification and the qualification as an MD are correct; in case of discrepancies between Kiwa Italia and the Organisation regarding classification and/or qualification as an MD, reference shall be made to § 5.1.2;
- Kiwa Italia has the capability to perform the required activities based on its scope of designation and the availability of sufficient, adequate resources and without conflict of interest;
- there are no differences compared with the data provided at the time of the Quotation request;
- the requirements of the certification service have been clearly defined and understood by both parties.

Kiwa Italia performs the review of the Application within a maximum timeframe of 30 Calendar Days[13] starting from the date of the email by which the Organisation has submitted the Application in complete form (as confirmed by Kiwa Italia) and ending on the date of communication of acceptance of the Application by Kiwa Italia. Where the need for clarifications, additions or amendments arises, the above-mentioned timeframe may be interrupted once only[14]; the Organisation shall have 20 Working Days from the communication by Kiwa Italia to provide what is required. In the absence of a reply from the Organisation within the above-mentioned timeframe, or where the additions are not considered adequate, the review of the Application shall have a negative outcome and Kiwa Italia shall proceed with the refusal of the Application (in whole or limited to certain devices), notifying it in writing with the relevant reasons and uploading the refusal to Eudamed.

It is understood that, in the event of refusal of the Application, the contract between Kiwa Italia and the Organisation shall not be finalised. In the event of partial refusal of the Application, Kiwa Italia shall submit to the Organisation a revised Quotation limited to the devices for which the Application is acceptable, consistent with the outcome of the review of the Application (including, where necessary, a revision of the applicable technical and economic terms, including timeframes), which shall fully replace the previously issued Quotation; therefore, upon signature of the revised Quotation by the Organisation, the contract shall be considered finalised on the date of the subsequent acceptance of the Application, which shall be communicated by Kiwa Italia to the Organisation by email, as indicated below.

In the event of a positive outcome of the review of the Application, Kiwa Italia, on the basis of further and/or more in-depth assessments of the documentation or information provided by the Organisation, may confirm the Quotation

[12] Intended solely as the *Manufacturer* as defined in Article 2 (30) or the natural or legal person referred to in Article 22(3).
[13] This timeframe applies to the conformity assessment procedures for which an Application has been submitted from 25 February 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.
[14] The interruption indicated applies to the conformity assessment procedures for which an Application has been submitted from 25 February 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.

referred to in the previous paragraph 5.2.3 or issue a new Quotation to the Organisation, replacing the previous one, containing a revision of the technical and economic terms (including timeframes) for the provision of the service.

In any case, by way of derogation from paragraph 3.2 of the "General Terms and Conditions", the contract between Kiwa Italia and the Organisation (referred to in Annex VII of the MDR, Point 4.3, second paragraph) shall be finalised by effect of and on the date of the communication of acceptance of the Application by Kiwa Italia to the Organisation, provided that the Organisation has previously signed the definitively applicable Quotation (i.e. the original one confirmed by Kiwa Italia or, where issued, the revised one) following the outcome of the review.

In this regard, Kiwa Italia shall communicate the acceptance of the Application to the Organisation by means of a specific written communication sent by email. It is understood that such communication of acceptance of the Application shall be considered as confirmation of the acceptance of the assignment by Kiwa Italia and shall therefore constitute an integral and essential part of the contract.

It is understood that the certification process is activated upon finalisation of the contract.

Where the Organisation requests the withdrawal of the Application (in whole or limited to certain devices), it shall send a written communication to Kiwa Italia signed by its Legal Representative (or a legally authorised person), stating the reasons. In such case:

1. if the withdrawal is communicated to Kiwa Italia before completion of the review of the Application, Kiwa Italia shall interrupt the review activities of the Application and the contract shall not be finalised;
2. if the withdrawal is communicated to Kiwa Italia after the review but before the issuance of the Certificate, Kiwa Italia shall interrupt any ongoing conformity assessment activities and close the certification plan. Therefore, where already finalised, the certification contract shall cease to have effect with respect to the devices subject to withdrawal.

It is specified that, in both cases 1 and 2 above, Kiwa Italia uploads such withdrawal to Eudamed in accordance with Article 53 (2) of the MDR in order to inform that such withdrawal occurred before the certification decision, and that from the date of the withdrawal communication by the Organisation, the Quotation/certification contract of Kiwa Italia shall cease to have effect with respect to the devices subject to such withdrawal.

In the event of withdrawal of the Application, the Organisation shall be required to pay Kiwa Italia the amounts relating to the activities performed up to that time and, where the certification contract has been finalised, also those relating to the closure of the certification plan, in accordance with the contract, as well as the fees relating to already planned activities, as provided for in Article 12 of this Regulation.

Kiwa Italia may also decide to withdraw the Application in the event of critical deficiencies identified during conformity assessment activities.

Where Kiwa Italia assesses that it is unable to comply with the maximum timeframe indicated above, for example due to force majeure, company closure periods of Kiwa Italia or unforeseen events related to resource availability, it undertakes to promptly inform the Organisation and shall agree with it on a new timeframe.

5.2.5 Planning of the conformity assessment activities

Following the activation of the certification process, Kiwa Italia proceeds with the planning of the conformity assessment activities. These are identified on the basis of the selected conformity assessment procedure and may include, as applicable:

1. planned audits at the site(s) of the Organisation (as described below) and critical suppliers (if applicable)
2. analysis of the technical documentation[15]
3. unannounced audits.

The conformity assessment activities referred to in points 1 and 2, carried out in accordance with Annex IX of the MDR during an initial certification or an extension, are performed in parallel, provided that the required contribution of the relevant technical documentation assessment is taken into account in the preparation of the audit programme (Stage 2).

Based on the type of Application submitted by the Organisation (e.g. new certification, extension, modification), Kiwa Italia determines which conformity assessment activities are required, reporting them in the Quotation, and defines the resources to be involved.

[15] Not applicable to certification activities referring to economic operators that carry out the activities mentioned in points (a) and (b) of Article 16(2) of the MDR.

The activities may be assigned either to internal personnel or to qualified external collaborators, in accordance with the requirements set out in Kiwa Italia procedures.

Where Kiwa Italia and the Organisation agree in writing on a cyclical review of the technical documentation (the Organisation submits the documents progressively for review), a plan for the submission of the different parts of the technical documentation shall be agreed, including any additional interruptions compared to those provided for in § 5.3.1, points 1 and 2.

Where it becomes necessary to subcontract part of the certification process, Kiwa Italia shall implement all necessary measures to ensure that the subcontractor complies with the requirements set out in Kiwa Italia rules. Responsibility for any subcontracted activities shall nevertheless remain with Kiwa Italia.

5.3 Assessment activities for certificate issuance

5.3.1 General Requirements

Kiwa Italia carries out the assessment activities for the issuance of certification within the following maximum timeframes[16]:

1. assessment of the QMS (Stage 1 and Stage 2): within a maximum of 120 Calendar Days starting from the first day of Stage 1 and ending on the date of completion of the final review (ref. § 5.3.5); where the Organisation is required to address findings or provide clarifications (ref. § 5.3.5), Kiwa Italia may interrupt the indicated maximum timeframe up to a maximum of 4 times in total[17]. Kiwa Italia may provide for 2 additional interruptions for each additional site, other than the central site of the Organisation's QMS, subject to on-site audit (including any sites of critical suppliers);
2. assessment of the technical documentation: within a maximum of 90 Calendar Days starting from the first day of the analysis and ending on the date of completion of the final review; where the Organisation is required to address findings or provide clarifications (ref. § 5.3.5), Kiwa Italia may interrupt the indicated maximum timeframe up to a maximum of 4 times[18]. The 90-day period and the number of interruptions shall be considered separately for each MD subject to sampling for assessment;
3. certification decision and issuance of the Certificate: within a maximum of 20 Calendar Days starting from the day following the completion of the last final review and ending on the day the Certificate is issued and uploaded to Eudamed. Where the Organisation is required to address findings, Kiwa Italia may interrupt the indicated maximum timeframe once only[19].

The maximum timeframes indicated above in points 1 and 2 shall apply if expressly agreed with the Organisation; otherwise, they shall start on the day following the date of completion of the review of the Application with a positive outcome (activation of the contract).

For Applications submitted before 25/02/2027 (and for recertification before 25/11/2027), unless otherwise agreed between the Organisation and Kiwa Italia in the contractual terms, the assessment activities of the QMS and of the technical documentation shall be positively completed within 1 year from the first day of assessment respectively of the QMS and of each MD for the technical documentation. Upon positive completion of the conformity assessment activities, the final review and decision process requires a maximum of 30 Working Days for each MD subject to certification, starting from the beginning of the process, i.e. after approval of the draft Certificate by the Organisation.

In order to ensure compliance with the above-mentioned timeframes, the Organisation shall provide full cooperation and shall comply, in turn, with the applicable deadlines relating to each phase of the conformity assessment.

In addition to the interruptions indicated above, Kiwa Italia shall interrupt the maximum timeframes of conformity assessment activities where consultations with Competent Authorities or the Expert Panel are required by the MDR. Such interruptions shall not be counted or accumulated with those indicated above. Kiwa Italia shall inform the Organisation in writing of the reason for the interruption and its expected duration.

[16] These timeframes apply to the conformity assessment procedures for which an Application has been submitted from 25 February 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.
[17] The number of interruptions indicated for the conformity assessment procedures for which an Application has been submitted from 25 February 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.
[18] The number of interruptions indicated for the conformity assessment procedures for which an Application has been submitted from 25 February 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.
[19] The number of interruptions indicated for the conformity assessment procedures for which an Application has been submitted from 25 February 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.

The duration of any of the above interruptions may be extended only if duly justified and if Kiwa Italia and the Organisation agree in writing on such extension.

The expiry of the above maximum timeframes or exceeding the maximum number of interruptions shall not constitute sufficient grounds for Kiwa Italia to refuse the issuance of a Certificate. Therefore:

- if the Organisation is unable to resolve findings or NC within the maximum allowed interruptions, the Application for certification shall lapse due to inability to resolve the recorded findings or NC. Where the Organisation still intends to obtain certification, it shall submit a new request; in such case, Kiwa Italia, when defining the number and duration of the conformity assessment activities, shall take into account, where possible, the activities already carried out;
- if Kiwa Italia is unable to comply with the above maximum timeframes, for example due to force majeure or unforeseen events related to resource availability, it undertakes to promptly inform the Organisation and shall agree with it on new timeframes.

5.3.2 Stage 1 Audit

The Stage 1 audit is carried out to verify the conformity of the Organisation's quality management system documentation to be certified with the applicable requirements of the MDR.

The QMS documentation shall include at least what is specified in Annex IX, Points 2.2 and 2.3 and Annex XI, Part A, Points 5 and 6 of the MDR, based on the selected conformity assessment Annex.

The Stage 1 audit is performed off-site, unless otherwise agreed between the parties. However, Kiwa Italia may decide to perform it at the Organisation's premises in specific cases (e.g. quantity and complexity of the documentation to be assessed).

For economic operators carrying out the activities referred to in points (a) and (b) of Article 16 (2) of the MDR, the QMS documentation shall define the structure, responsibilities, procedures, processes and resource management necessary to achieve compliance with the provisions of Article 16 (3) of the MDR.

At the end of the Stage 1 audit, Kiwa Italia sends to the Organisation the Stage 1 audit report summarising the outcome, including any findings. The date of transmission of the report interrupts the calculation of the maximum timeframes for completing the assessment. The Organisation shall acknowledge the report and its results, sign it and send it to Kiwa Italia.

Where findings are identified in the report, the Organisation shall submit to Kiwa Italia, using the appropriate forms, within 20 Working Days from the date of receipt of the Stage 1 audit report, the corrective action plan (hereinafter "CAP"), including the analysis of root causes that generated the findings, the proposed corrections and corrective actions to be implemented for their resolution, including the related implementation timeline and the date on which the revised documentation will be fully submitted to Kiwa Italia; such date shall not exceed 6 months from the recording of the findings. The date of submission of the CAP by the Organisation restarts the calculation of the maximum timeframes for completing the assessment.

If the Organisation is unable to meet the 20 Working Days deadline for submission of the CAP, it shall inform Kiwa Italia at least 5 Calendar Days before the expiry of the 20 days; in such cases, Kiwa Italia and the Organisation shall agree on an extension of the interruption, the end of which shall coincide with the new CAP submission date.

The Organisation may also decide not to submit the CAP and to terminate the assessment process by notifying Kiwa Italia of the withdrawal of the Application for certification (§ 5.2.4) within 5 Working Days from receipt of the Stage 1 audit report. In the absence of a reply from the Organisation within the above deadline, Kiwa Italia shall consider the certification process ongoing and shall await receipt of the CAP as described above.

The LA evaluates the CAP received from the Organisation, accepting it or not, and Kiwa Italia shall inform the Organisation accordingly, also indicating any supplementary assessment days, determined based on the number of findings, necessary for their closure; the costs for CAP assessment and supplementary assessments are additional and shall be charged to the Organisation based on the rates contractually agreed. If the CAP is not accepted by Kiwa Italia, the Organisation shall submit a revised CAP according to the same modalities and timelines described above; the date of communication of non-acceptance of the CAP by Kiwa Italia interrupts the maximum timeframe for this conformity assessment.

Following acceptance of the CAP, Kiwa Italia proceeds as follows.

Where only non-critical findings are present, Kiwa Italia plans and performs the Stage 2 audit; the maximum time between successful completion of Stage 1 and the first day of Stage 2 shall not exceed 30 Calendar Days. During such audit, verification of closure of non-critical findings is also performed (with possible supplementary days), and therefore the revised documentation shall be available in accordance with the CAP.

Where critical findings are present, Kiwa Italia plans a supplementary assessment to achieve closure of such findings based on the date of submission of the documentation set in the CAP. It shall not be possible to plan and perform the Stage 2 audit as above until such findings have been resolved and positively closed. The date on which Kiwa Italia informs the Organisation of the acceptance of the CAP interrupts the maximum timeframe for this conformity assessment; such timeframe resumes when the Organisation submits the revised documentation to Kiwa Italia. If the Organisation fails to meet the deadline set in the CAP for submission of the revised documentation, it shall inform Kiwa Italia at least 15 Calendar Days before the established date to allow rescheduling of the activities. In case of delayed submission without prior notice, the Organisation shall pay the amount corresponding to the days previously scheduled for the supplementary assessment. Once the documentation has been received, the LA carries out the supplementary assessment. In case of a negative outcome, the process continues according to the rules above starting from the submission by the Organisation of a further CAP for resolution of findings. In case of a positive outcome of the supplementary assessment, the process proceeds with the planning and execution of Stage 2 as described above.

5.3.3 Stage 2 Audit

The Stage 2 audit is carried out at the locations where the activities relating to the devices to be certified are performed, with the aim of assessing that the quality management system verified during the Stage 1 audit ensures that such devices comply with the relevant provisions of the MDR, with reference to all phases of the device life cycle (from design to final quality control up to continuous surveillance).

The Stage 2 audit is planned in such a way as to verify the Organisation's processes, in particular with regard to design and development, production and process controls, product documentation, purchasing controls including verification of purchased devices, corrective and preventive actions, including those relating to post-market surveillance and PMCF; moreover, this audit shall examine all requirements and provisions adopted by the Organisation, including those relating to compliance with the General Safety and Performance Requirements set out in Annex I of the MDR.

In defining the aspects to be verified, Kiwa Italia determines which critical suppliers shall be subject to audit. Kiwa Italia may decide, also based on the results of periodic audits, not to perform the audit at a critical supplier, provided that the Organisation is able to demonstrate adequate control over its critical suppliers, where the critical supplier:

1. holds a valid certificate issued by Kiwa Italia with reference to the schemes: ISO 13485, MDR Annex IX or XI, or ISO 9001, for the processes/services/products supplied to the Organisation (related to the MD to be certified);

   or

2. holds a valid certificate issued by another Accredited Certification Body or Notified Body for schemes[20] equivalent to those referred to in the previous point.

The above points do not apply to critical suppliers that carry out the entire production of the MD, for which an audit shall always be required before certification issuance and at least every three years during the certification cycle.

The LA prepares the Stage 2 audit plan, which is sent to the Organisation. Any modifications to this plan may be agreed based on the Organisation's needs during the audit, at the opening meeting.

Kiwa Italia may perform sampling activities and laboratory testing on the medical device to be certified (cf. § 4.5.3).

During the Stage 2 audit, the LA also prepares the periodic conformity assessment programme. This programme constitutes the basis for the subsequent detailed planning of each individual audit.

During the Stage 2 audit, Kiwa Italia reserves the right to issue NCs in the absence of resolution and closure, even partial, of the non-critical findings issued during the Stage 1 audit.

At the end of the audit, the LA provides a copy of the report to the Organisation, which shall sign it. In the event of NCs, the date of delivery of the report by the LA interrupts the calculation of the maximum timeframes for completion of the assessment.

[20] In the case of testing laboratories or calibration centres, ISO 17025 accreditation issued by a recognised Accreditation Body, or authorisation in accordance with Good Laboratory Practice, or laboratories that are internationally recognised testing centres, are also considered valid.

Following any NCs identified during the audit, the subsequent management of the CAP, of the interruptions of the maximum timeframes indicated and, where applicable, of the submission of revised documentation, shall take place according to the same modalities described for Stage 1 findings.

In the case of multisite organisations, interruptions of the maximum timeframes may also apply in the event of issues related to audit planning at the sites (e.g. limited site availability); in particular, the interruption shall be represented by the period between the last day of audit at the Organisation's central site and the first day of audit at the individual site and shall not exceed 6 months.

In the case of Major NCs, within 6 months from the last day of the Stage 2 audit, the implementation of corrections and corrective actions shall be verified through a supplementary assessment, according to the assessment methods defined by the LA (audit at the Organisation's premises and/or document analysis, where applicable). Beyond this limit, Kiwa Italia may, at its discretion, evaluate subsequent actions, including, for example, restarting a new certification process or interrupting it; in the latter case, the Application shall be refused, with subsequent upload of the refusal to Eudamed. Such actions may also be determined based on significant changes to the relevant regulatory context or any changes to the Organisation's processes or sites. In the case of significant changes, the maximum period of 6 months may be reduced at the discretion of Kiwa Italia.

Following the closure of Major NCs, the Organisation shall submit to Kiwa Italia the revised quality management system documentation in full.

In the case of Minor NCs, verification of implementation and effectiveness of corrections and corrective actions is carried out during the first scheduled surveillance audit. Depending on the number and content of Minor NCs, Kiwa Italia may establish additional time for their closure, the costs of which shall be charged to the Organisation based on the contractually agreed rates.

5.3.4 Initial assessment of technical documentation

The assessment of the technical documentation is generally conducted and completed before the performance of Stage 2; however, in the case of conformity assessment carried out in accordance with Annex IX, Chapter I, it may be conducted in parallel with Stage 2, without prejudice to what is stated in § 5.2.5.

The technical documentation shall include at least the elements set out in Annexes II and III of Regulation (EU) 2017/745, except for custom-made Class III implantable devices, which shall include the elements set out in Annex XIII, and shall be prepared in accordance with the structure of the Team NB Position Paper "*Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of Medical Device Regulation (EU) 2017/745*" (available at https://www.team-nb.org/team-nb-documents/).

The assessment of the technical documentation is carried out off-site, unless otherwise agreed between the parties or in specific cases determined by Kiwa Italia, by personnel with the necessary technical and clinical competence relating to the scheme and the type of product to be certified. However, Kiwa Italia may decide, in specific cases (e.g. risk class of the MDs, quantity and complexity of the documentation to be assessed), to carry out the analysis of the technical documentation at the Organisation's premises.

The assessment of the technical documentation serves to verify compliance with the applicable requirements of the MDR relating to the product to be certified and is intended as the verification of the solutions adopted by the Organisation to meet the minimum requirements relating to all phases of the life cycle of the MD subject to certification, including transport, installation, use and decommissioning, in order to ensure the safety and performance claimed in its intended purpose. Particular attention shall be paid to the solutions adopted in the design, manufacturing, packaging, labelling and use phases, verifying that all risk management conditions have been met, including those provided for by ISO 14971, and verifying that safety principles have been applied in a manner consistent with the current level of knowledge and the state of the art.

Documents relating to pre-clinical and clinical data and test reports shall also be verified. The results of tests performed by the Organisation included in the technical documentation shall be performed by external laboratories accredited according to ISO 17025, or testing centres authorised for Good Laboratory Practice (GLP), or test centres recognised by scientific bodies of proven authority (e.g. IECEE CB, university centres of excellence). The use of other laboratories or the Manufacturer's internal laboratories is accepted where the laboratory has been adequately qualified by the Organisation according to the requirements of ISO 17025 and produces a test report containing the minimum information required by ISO 17025. Kiwa Italia reserves the right to request additional tests if deemed necessary for the conformity assessment. Such additional tests shall be at the expense of the Organisation and the related costs shall be charged in addition based on the contractually agreed rates.

Depending on the class of the MDs subject to certification, Kiwa Italia shall assess whether to carry out the analysis of the technical documentation for all MDs subject to certification or on representative samples for generic groups or categories of products, in accordance with Article 52 of the MDR.

The Organisation shall maintain for Kiwa Italia a controlled updated copy of the technical documentation and make it available upon request at any time and during assessment activities, throughout the entire period of validity of the assessment contract with Kiwa Italia.

At the end of the analysis of the technical documentation, the relevant reports (technical and clinical) are sent to the Organisation summarising the outcome. The date of sending the report by Kiwa Italia interrupts the calculation of the maximum timeframes for completing the assessment.

In the event of findings, Kiwa Italia shall verify their resolution before issuing the certification; depending on their number and content, Kiwa Italia shall establish additional time for their closure (supplementary assessment), the costs of which shall be charged to the Organisation based on the contractually agreed rates.

Where the Organisation does not wish to proceed with the certification process, it shall notify an official withdrawal of the Application for certification within 5 Calendar Days from receipt of the report (see § 5.2.4). In the absence of a reply from the Organisation within the above-mentioned deadline, Kiwa Italia shall consider the certification process ongoing; in such case, within 20 Working Days from receipt of the report, the Organisation shall send to Kiwa Italia the signed reports and, in case of findings, also the CAP completed using the appropriate forms, including the exact date on which the revised technical documentation will be sent in full to Kiwa Italia, which shall in any case not exceed 6 months from the recording of the findings. The date of submission of the CAP by the Organisation shall resume the calculation of the maximum timeframes for completion of the assessment.

The technical and/or clinical personnel of Kiwa Italia shall evaluate the CAP received, accepting it or not, and Kiwa Italia shall inform the Organisation, also indicating the days of supplementary assessment required for closing the findings; the date of such communication interrupts the calculation of the maximum timeframes for completion of the assessment.

In case of non-acceptance of the CAP, the Organisation shall submit a new CAP and the process continues according to the rules above.

In case of acceptance of the CAP, Kiwa Italia plans any supplementary assessment based on the date on which the Organisation has indicated it will submit the revised documentation. If the Organisation fails to meet the planned submission date of the revised documentation, it shall inform Kiwa Italia at least 15 Calendar Days before the deadline in order to allow rescheduling. In case of failure to submit the documentation and/or failure to provide prior notice within the above-mentioned timeframe, the Organisation shall pay the amount corresponding to the days previously communicated for the supplementary assessment.

Once the revised technical documentation has been received, the technical and/or clinical personnel shall carry out the supplementary assessment. The date of receipt of the documentation restarts the calculation of the maximum timeframes for completion of the assessment.

In the event of a negative outcome of the supplementary assessment, the process continues according to the above rules and therefore the Organisation shall submit a further CAP to resolve the findings.

In the event of a positive outcome of the supplementary assessment, the certification process may proceed with the final review.

5.3.5 Final review

The final review is carried out by Kiwa Italia personnel with technical expertise (Final Reviewer) who have not been involved in the conformity assessment activities, in order to:

1. verify that the reports and supporting documentation required for the decision-making phase, including those relating to the resolution of non-conformities identified during the assessment, are complete and sufficient with respect to the scope of the Application for certification;
2. verify that there are no unresolved non-conformities that would prevent the issuance of the Certificate.

If, following the review, requests for clarifications or for additional data arise, these shall be requested from the Organisation, specifying the timeframe for the submission of the clarifications. The date of communication of the request for clarifications by Kiwa Italia interrupts the calculation of the maximum timeframes for completion of the

conformity assessment activities indicated in § 5.3.1, points 1 and 2. The date of receipt of the clarifications from the Organisation restarts the calculation of the above-mentioned maximum timeframes.

Upon completion of this review, the certification decision shall be carried out.

5.3.6 Decision for initial certification

The decision for certification is carried out by Kiwa Italia personnel with technical expertise who have not been involved in the conformity assessment activities, on the basis of the results of the conformity assessment activities performed and the outcomes of the final review. During the certification decision process, the decision-making personnel (Decision Maker) may request clarifications from the audit team, additional conformity assessment activities, additional information, limitations and/or specific conditions to the certification (see § 5.9).

Any assessment differing from that recorded by the personnel who performed the conformity assessment activities shall be communicated to the Organisation.

If, following the decision evaluation, requests for clarifications or additional data arise, these shall be requested from the Organisation, specifying the timeframe for the submission of the clarifications. The date of communication of the request for clarifications by Kiwa Italia interrupts the calculation of the maximum timeframes for the issuance of the Certificate indicated in § 5.3.1, point 3. The date of receipt of the clarifications from the Organisation restarts the calculation of the above-mentioned maximum timeframes.

In the event of a positive outcome of the decision process, Kiwa Italia issues the Certificate of conformity, which is sent to the Organisation.

The validity of the Certificate is established based on the characteristics of the product to be certified, such as, for example, the risk classification and clinical evaluation aspects, etc.; however, such validity shall not exceed 5 years from the date of issuance.

Once the certification has been received, the Organisation shall apply the notification number 0476, identifying Kiwa Italia, to the devices subject to certification.

In the event of a negative outcome of the decision process, Kiwa Italia refuses the certification and sends a communication to the Organisation indicating what has been established during the certification decision phase and the related actions to restart the certification process, if applicable. The refusal of certification may also occur following negative opinions expressed by other Competent Authorities consulted, as provided for by Regulation 2017/745.

The refusal of certification is uploaded to Eudamed.

5.4 Surveillance activities

5.4.1 General Requirements

The performance of the surveillance activities provided for in the certification cycle is subject to the regular payment of previous activities by the Organisation. Otherwise, Kiwa Italia reserves the right not to carry out the planned activities and to proceed with the suspension or withdrawal of the Certificate.

Before the surveillance activities, Kiwa Italia shall request the submission of the following updated documents: technical documentation, quality management system documents updated since the previous assessment activity, evaluation reports of clinical data, including post-market surveillance and post-market clinical follow-up data, PSUR and PSR, and where applicable the summary referred to in Article 32 of Regulation 2017/745. The documentation shall in any case be provided at least 30 Working Days before the start date of the surveillance activities.

It is the responsibility of the Organisation to send to Kiwa Italia correct and updated documentation, in accordance with the minimum frequencies established by the MDR (based on the type of device subject to certification).

In the case of Major NCs affecting the safety of the product, the certification shall be suspended until verification of the resolution of the NCs (or, where possible, reduced).

5.4.2 Scheduled surveillance audits

Scheduled surveillance audits are carried out once every 12 months, considering that the first surveillance audit shall be performed within 12 months from the month of the decision (due date). Anticipations or postponements of up to 3 months from the due date may be allowed at the sole discretion of Kiwa Italia.

Surveillance audits are always carried out at the locations where the activities related to the products subject to certification are performed.

The purpose of the scheduled surveillance audit is to verify that the Organisation applies the approved quality management system and the post-market surveillance plan[21], to verify the maintenance of the conditions that led to the granting of certification, and to verify any changes to processes or products (see § 5.5).

The surveillance audit is based on sampling of the activities subject to certification and shall ensure:

- the continuous application of the entire quality management system throughout the certification cycle;
- an assessment of the technical documentation as defined in the periodic programme issued following the certification audit;
- verification of any critical suppliers, as defined in the periodic programme issued following the certification audit;
- evaluation of the resolution of non-conformities identified during previous audits, as well as evaluation of the implementation and effectiveness of corrective actions adopted by the Organisation. Based on the number and content of the Minor NCs to be verified, Kiwa Italia may establish additional time for their closure, which shall be communicated to the Organisation during the planning phase of the surveillance audit; the related costs shall be charged in addition to the Organisation based on the contractually agreed rates;
- the possible performance of appropriate tests to verify the proper functioning of the quality management system; during such audits, Kiwa Italia may carry out sampling and laboratory testing on the certified medical device (see § 5.4.5). For Class III MDs, tests shall always be carried out on approved parts and/or materials which are essential for the integrity of the MD, including, where applicable, verification that the quantities of parts and/or materials produced or purchased correspond to the quantities contained in the finished MDs. Where Kiwa Italia identifies a discrepancy between the sample taken from manufactured devices and the specifications contained in the technical documentation, it shall suspend or withdraw the relevant Certificate, or impose reductions/limitations where applicable.

At the end of the audit, the LA provides a copy of the audit report, which shall be signed by the Organisation.

In the event of NCs identified, the Organisation shall submit to the LA, within 20 Working Days and using the appropriate forms, the CAP and, for Major NCs only, also the date on which the necessary documentation for their resolution will be submitted to Kiwa Italia. The LA shall assess the proposed actions, accepting them or not, and shall communicate the outcome to the Organisation. The communication of acceptance of the CAP shall also be sent by the RGA to Kiwa Italia. The report shall be considered confirmed by Kiwa Italia if no further notifications are issued to the Organisation within 60 Calendar Days from the date of approval of the CAP. During subsequent internal periodic approval activities, should the need arise to amend the contents of the report (e.g. modification of the weight of a finding), Kiwa Italia shall inform the Organisation together with the actions to be taken.

Verification of the implementation and effectiveness of corrections and corrective actions related to Minor NCs shall be carried out by Kiwa Italia during the subsequent scheduled surveillance audit. Depending on the number and content of the Minor NCs, Kiwa Italia may establish additional time for their closure, the costs of which shall be charged in addition to the Organisation based on the contractually agreed rates.

Verification of the implementation and effectiveness of corrections and corrective actions related to Major NCs shall be carried out through a supplementary assessment, according to methods defined by the LA (audit at the Organisation's premises and/or through documentary evidence where possible). This assessment shall be carried out within the timeframes established by Kiwa Italia and in any case no later than 6 months from the surveillance audit; beyond this limit, Kiwa Italia shall decide on the consequent actions at its discretion. Where the outcome of the above assessment is positive, certification is confirmed. Where the Organisation fails to implement the agreed actions for the resolution of findings within the allowed timeframes, certification may be suspended or withdrawn.

5.4.3 Technical documentation analysis during surveillance

Within the surveillance activities, Kiwa Italia performs an annual verification of the technical documentation relating to certified products as provided for in the periodic programme. The verification is normally carried out in conjunction with the scheduled surveillance audits and may be performed on-site or off-site, depending on the planning needs of the activity.

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

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

For Class III devices and implantable devices, Kiwa Italia shall also perform verification of the periodic safety update report (PSUR), through the Eudamed system, according to the frequencies established by the MDR; it is the responsibility of the Organisation to upload such report to Eudamed in accordance with the timelines provided for by the MDR, based on the class of the device subject to certification.

In the event of findings, within 20 Working Days from the date of receipt of the reports, the Organisation shall send to Kiwa Italia the signed reports and, in the case of findings, also the CAP completed using the appropriate forms received, including the exact date on which the revised technical documentation will be sent in full to Kiwa Italia. The technical and/or clinical personnel of Kiwa Italia shall evaluate the CAP received, accepting it or not, and Kiwa Italia shall inform the Organisation, also indicating the days of supplementary assessment necessary for the closure of such findings, the costs of which shall be charged in addition to the Organisation based on the contractually agreed rates.

In case of non-acceptance of the CAP, the Organisation shall submit a new CAP and the process continues according to the rules set out above.

In case of acceptance of the CAP, Kiwa Italia plans any supplementary assessment based on the date on which the Organisation has indicated it will send the revised documentation. If the Organisation fails to meet the planned submission date of the revised documentation, it shall inform Kiwa Italia at least 15 Calendar Days before the established date to allow rescheduling. In case of failure to submit the documentation and/or failure to provide prior notice within the above timeframes, the Organisation shall pay the amount corresponding to the days previously communicated for the supplementary assessment.

Once the revised technical documentation has been received, the technical and/or clinical personnel shall carry out the supplementary assessment:

- within 3 months from receipt of the findings by the Organisation in the case of critical findings;
- during the subsequent surveillance in the case of non-critical findings.

Kiwa Italia may define different timeframes depending on the content of the findings and the actions required for their resolution.

In the event of a negative outcome of the supplementary assessment, the process continues according to the rules set out above; therefore, the Organisation shall submit an additional CAP for the resolution of the findings.

In the event of a positive outcome of the above assessment, certification is confirmed.

Where the Organisation fails to implement the agreed actions for the resolution of findings within the allowed timeframes, certification may be suspended or withdrawn.

In the case of subsequent internal periodic approval activities carried out by Kiwa Italia on the content of the technical documentation analysis reports, where changes are required (e.g. change in the weight of a finding), Kiwa Italia shall inform the Organisation together with the actions to be implemented.

5.4.4 Unannounced surveillance audits

Kiwa Italia carries out unannounced audits at least once every 5 years, at the locations where the activities related to the products subject to certification are performed (these shall also include the premises of critical suppliers), in order to verify the daily compliance with requirements by the Organisation.

Kiwa Italia shall perform such audits randomly and may increase their frequency, for example in cases where the devices present a high potential risk and/or are frequently non-compliant and/or where there are specific reasons to suspect non-conformity of the devices and/or the Organisation. Furthermore, based on the appropriate sample of MDs to be verified, Kiwa Italia shall determine the specific duration of such audit; this duration shall be communicated to the Organisation during the audit itself. The minimum duration is 1 day with 2 evaluators.

In order to ensure the proper execution of unannounced audits, the Organisation undertakes to provide Kiwa Italia with information on the periods of the year during which the manufacture of the medical devices subject to certification is not foreseen (company closures, holidays, production shutdowns, etc.); similar information shall also be provided with reference to Critical suppliers.

The Organisation also undertakes to include, in the contracts governing the relationship with its critical suppliers, prior authorisation for access by Kiwa Italia to the premises/sites where the critical supplier's activities are carried out. Where a visa is required to perform the audit at the supplier's premises, the Organisation shall provide a letter of invitation including the relevant dates (signature and visit). This requirement shall be communicated by Kiwa Italia to the Organisation during the unannounced audit, which shall be completed following the verification at the critical supplier.

The Kiwa Italia audit team shall present itself at the locations where the activities related to the products subject to certification are carried out, with an identification letter. The Organisation may contact Kiwa Italia offices and request confirmation of the activity.

Within the context of unannounced audits, Kiwa Italia performs checks on an appropriate sample of recently manufactured medical devices[22], preferably taken from the manufacturing process in progress at the time of the audit, in order to verify, including through testing, their conformity with the technical documentation and applicable legal provisions. Testing on MDs is carried out as detailed in § 5.4.5.

Where a discrepancy is identified between the sample taken from manufactured devices and the specifications contained in the technical documentation, the corresponding Certificate shall be suspended or withdrawn, or specific reductions/limitations shall be imposed (where applicable).

Where the Organisation or its critical suppliers refuse to receive an unannounced audit, the Organisation shall formalise such refusal (on headed paper with stamp and signature) and indicate the reasons why it was not possible to perform the audit. Kiwa Italia reserves the right to evaluate the consequent actions, which may lead to suspension or withdrawal of the certification. The Organisation shall be promptly informed of the decisions taken.

Kiwa Italia may decide to perform unannounced audits in combination with the scheduled surveillance audit, either before its start or after its completion.

At the end of the unannounced audit, the LA provides a copy of the audit report to the Organisation and collects records of the tests carried out on the day of the audit, completed by the personnel appointed by the Organisation and/or the critical supplier responsible for performing the tests.

Where tests are carried out by an external laboratory, or where test results require longer timeframes than the audit days, the report shall be finalised by the LA only after the test results are available and shall be sent to the Organisation together with the test reports of the external laboratory. If requested by the Organisation, a draft not finalised report may be provided.

In the event of a negative outcome of laboratory tests, a new sampling and repetition of tests may be carried out, the costs of which shall be charged additionally to the Organisation based on the contractually agreed rates.

The management of the results of unannounced audits shall follow the same modalities described in § 5.4.2.

5.4.5 Product testing activities

Kiwa Italia may perform product testing not only during unannounced audits, but also during any surveillance audit, depending on the class of the device, or at any time during the certification cycle, for example on the basis of reports, complaints or cases of suspected product non-conformity, etc.

Tests may be carried out by taking samples from the Organisation, or also following sampling of certified devices from the market. The above-mentioned tests may be performed:

- at the premises of the Organisation or of the critical supplier, directly by the designated personnel under the supervision of the audit team, which shall also verify the use of competent personnel, suitable environments and measuring instruments calibrated by accredited calibration centres and therefore ensuring metrological traceability;
- at Kiwa Italia laboratories or at external laboratories qualified by Kiwa Italia. In particular cases, when tests involve protocols that are not easily performed, laboratories recommended by the Organisation may be selected, provided that the test is carried out under the supervision of a Kiwa Italia expert.

Where an external laboratory is used, samples shall be packaged and sent by the Organisation to the laboratory as indicated by the LA, ensuring the integrity of the sample packaging and that no alteration occurs.

5.5 Changes and Extensions

5.5.1 Changes

The Organisation has primary responsibility in the process of implementing changes, which includes their identification, analysis, recording and implementation. The Organisation intending to make changes relating to:

- the approved quality management system[23] or the range/type of certified products;

[22] With the exception of MDs referred to in Article 52(8), second paragraph (custom-made implantable Class III MDs).
[23] For example: production processes and technologies, human resources or equipment used, changes to production sites, change of critical suppliers.

- the approved design[24] and software of the device;
- the intended purpose, conditions of use and claims attributed to the device;
- the approved type of device;
- any substance incorporated or used in the manufacture of the device, with particular reference to medicinal substances, tissues or cells of animal origin and their derivatives, and other substances referred to in the specific procedures of Annex VII, Point 4.5.6 of the MDR;
- administrative aspects such as, for example, a change of name and/or company name, or a change of the person responsible for regulatory compliance or of the Legal Representative;
- corporate structure, for example mergers, demergers, lease of a business unit

has the sole responsibility to appropriately categorise the changes[25] and to adopt the consequent actions, depending on the type and impact of the variation. For the purposes of this Regulation, the categorisation of changes is as follows:

1. **changes to be notified subject to prior approval** by Kiwa Italia; the Organisation shall promptly notify any project it intends to undertake for the following changes, which require prior approval by Kiwa before their implementation:
   - substantial changes;
   - changes to the approved device subject to prior approval;
   - administrative changes subject to prior approval.
2. **changes to be notified not subject to prior approval** by Kiwa Italia; the Organisation shall notify such changes for information purposes only, even though they do not require prior approval by Kiwa Italia for their implementation; such changes may require administrative activities such as: revision of certificates or updates of information in EUDAMED, which Kiwa Italia shall perform.
3. **changes not to be notified to** Kiwa Italia; changes not falling within the above categories, which the Organisation may implement without submitting a request for prior approval or notification to Kiwa Italia.

For examples falling within the above categorisation of changes, reference shall always be made to the applicable MDCG and/or NBCG Guidelines in force, applicable to the MDR.

Changes referred to in points 2 and 3 shall be subject to verification by Kiwa Italia on a sampling basis, within surveillance or recertification audits. For changes referred to in point 2, Kiwa Italia shall inform the Organisation in writing of the receipt of such notification and of any administrative activities to be carried out. Any related costs shall be charged to the Organisation in accordance with the conditions set out in the existing contract or through the issuance of a dedicated Quotation.

In the case of changes referred to in points 1 and 2, the Organisation shall notify them promptly using the MOD PO 09 MED_MDR form by completing only the sheet *"MDR_Required Service Change"*. Requests for changes referred to in points 1 and 2 communicated during periodic document assessments and/or audits shall not be processed.

The request for change shall include a self-contained report containing at least the following information:

a) categorisation of the change and justification;

b) rationale for the change and assessment of its impact on conformity with the General Safety and Performance Requirements (GSPRs) with respect to the approved device or range of approved devices and the QMS;

c) clear description of the change to be implemented, including comparison with the approved device, range of devices and/or QMS (including images, where applicable);

d) implementation plan for the change, including necessary steps, verification and validation activities and implementation timelines; the activities set in the plan shall ensure compliance with applicable regulatory requirements;

e) list of documentation to be modified (technical documentation and QMS procedures) and the documents supporting the change;

[24] Including materials, packaging, and safety and performance requirements.
[25] The process aimed at establishing whether a change must be reported and, if so, whether it requires prior approval from Kiwa or a simple informational communication.

f) statement regarding relevance to conformity with the requirements set out in Annex IX, section 2.2 of the MDR, or Annex XI, Part A of the MDR in case of changes to the QMS.

For changes referred to in point 2 above, the report shall include only the information indicated in points a), b) and c).

In some cases and subject to agreement with Kiwa Italia, the Organisation may group and notify several changes subject to prior approval affecting the QMS or the approved device. Where multiple changes are grouped for simultaneous implementation, their combined effect shall also be assessed. In such cases, where possible, a single MOD PO 09 MED_MDR form - sheet "MDR_ Required Service Change" may be used.

Once the above documentation has been received, Kiwa Italia shall confirm in writing whether it is complete or whether additional information is required. Requests for additional information shall be limited to what is necessary to complete this evaluation phase.

Kiwa Italia processes change requests in order of receipt of the relevant communication. In cases where changes qualify as extensions of certification, reference shall be made to § 5.5.2.

For the purpose of approving the change, based on the information and documents received, Kiwa Italia:

a) evaluates the change projects submitted and determines the consequent actions (e.g. documentary and/or on-site assessments, administrative evaluations for the revision of EU certificates), which are communicated to the Organisation within a maximum of 30 Calendar Days[26] from the date of the email by which the Organisation submitted the complete documentation (as confirmed by Kiwa Italia); subsequently, Kiwa Italia prepares and sends a quotation, which, once signed by the Organisation, becomes an integral part of the existing contract and allows proceeding with the subsequent phases;

b) carries out the conformity assessment activities provided for in the contract within a maximum of 90 Calendar Days[27] starting from the first day of the first planned assessment activity and ending when Kiwa Italia communicates in writing its approval of the change to the Organisation (clearance letter). Where the change concerns multiple MDs, the 90 days shall apply to each MD subject to sampling;

c) issues the amended Certificate, where necessary, within a maximum of 20 Calendar Days[28] starting from the day following notification of approval referred to in previous point a) and ending with the upload of the amended Certificate to Eudamed. The expiry date of the Certificate shall remain unchanged.

For Applications submitted before 25/02/2027, unless otherwise agreed between the Organisation and Kiwa Italia in the contractual terms, the conformity assessment activities related to the change shall be completed positively within 1 year from the first day of assessment (for documentation, each MD shall be considered individually for timing purposes). Upon positive completion of conformity assessment activities, the final review and decision process requires a maximum of 30 Working Days for each MD subject to change, starting from the beginning of the process, i.e. after approval of the draft Certificate by the Organisation.

Where there are ongoing assessments relating to the same technical documentation, Kiwa Italia shall perform the assessments aimed at approving the change only after completion of those in progress.

The Organisation shall not implement any change referred to in point 1 before receiving formal written approval from Kiwa Italia.

In the case of findings classified as critical or major, approval of the change cannot proceed before verification of their closure.

Management of findings resulting from document assessments shall be carried out as indicated in § 5.3.4. *Initial assessment of technical documentation*. Management of findings resulting from audits shall be carried out as indicated in § 5.3.3. *Stage 2 Audit*.

Where the Organisation is required to address findings or respond to requests from Kiwa Italia necessary for the execution of the activities referred to in above points a) and b), the related timeframes may be interrupted up to a maximum of 5 times[29] in total.

[26] This timeframe applies to the conformity assessment procedures for which an Application has been submitted from 25 February 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.
[27] This timeframe applies to the conformity assessment procedures for which an Application has been submitted from 25 February 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.
[28] This timeframe applies to the conformity assessment procedures for which an Application has been submitted from 25 February 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.

Expiry of the maximum timeframes or exceeding the maximum number of interruptions shall not in itself constitute sufficient grounds for Kiwa Italia to refuse approval of the change. Therefore:

- where the Organisation is unable to resolve findings or NCs within the maximum allowed interruptions, approval of the change shall lapse due to inability to resolve the recorded findings or NCs. Should the Organisation still intend to obtain approval of the change, it shall submit a new request; in such cases, when determining the number and duration of the conformity assessment activities, Kiwa Italia shall, wherever possible, take into account the activities already performed;
- where Kiwa Italia is unable to meet the maximum timeframes, for example due to force majeure or unforeseen events related to resource availability, it undertakes to promptly inform the Organisation and agree on a new timeframe.

For certain types of changes referred to in point 1, the Organisation may submit to Kiwa Italia a predetermined change control plan (hereinafter "PCCP"). The PCCP shall be notified following the same procedures as for changes under point 1 and, with reference to above point d), shall also include expected results and acceptance criteria, allowing Kiwa Italia to assess and approve it. In the event of a positive assessment, Kiwa Italia shall communicate approval of the PCCP to the Organisation. The Organisation shall implement the change strictly in accordance with the approved PCCP. Where the PCCP is implemented as approved and results comply with the defined acceptance criteria, Kiwa Italia shall not issue further communications or approvals for the change related to the approved PCCP, without prejudice to the fact that such change shall be subject to sampling-based verification within surveillance audits. For certain PCCPs, Kiwa Italia may require additional communication/information obligations and/or define supplementary assessments to confirm approval of the change. In such cases, Kiwa Italia shall specify these requirements in the PCCP approval communication.

Where the Organisation introduces changes or deviations to the PCCP (e.g. elimination of tests and sampling activities not performed or removed), or where results do not meet acceptance criteria, the Organisation shall promptly inform Kiwa Italia. In such cases, approval of the PCCP shall lapse and approval of the change by Kiwa Italia shall follow the process described for changes under point 1.

In the event of a negative assessment of the PCCP, Kiwa Italia shall inform the Organisation of the non-approval and of the subsequent actions to be undertaken, in line with the provisions applicable to changes under point 1.

5.5.2 Extensions

Any addition to the contents of the scope of the Certificate (products and/or sites of the Organisation) is considered an extension of the certification.

The Organisation shall inform Kiwa Italia in advance in the event of extensions to the certification, following the process previously described starting from § 5.2. Requests for extensions submitted during periodic document assessments or during periodic audits at the Organisation's premises shall not be processed.

Kiwa Italia processes extension requests in order of receipt. In cases where there are ongoing assessments relating to the same technical documentation, Kiwa Italia shall perform the assessments for the extension only after completion of those in progress.

Based on the type of extension requested, Kiwa shall determine the appropriate certification process, including all or part of the conformity assessment activities described in § 5.2.5, by preparing a Quotation to be sent to the Organisation. Such Quotation, once signed by the Organisation, constitutes the formal Application for extension and forms an integral part of the existing contract between Kiwa Italia and the Manufacturer.

The conformity assessment activities defined for extensions shall be subject to the same maximum timeframes and related interruptions as those applicable to analogous activities for initial certification as defined in § 5.3.1, including their date of application, except that the terms "Stage 1" and "Stage 2" shall be understood as "audit".

The expiry date of the Certificate shall not be modified in the event of extension of the Certificate.

5.6 Recertification

5.6.1 General Requirements

The Organisation shall submit an application for recertification of product certificates at least 12 months before their expiry date.

[29] The number of interruptions indicated applies to the conformity assessment procedures for which an Application has been submitted from 25 February 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.

The application for recertification, the preparation and acceptance of the quotation, the review of the Application and the activation of the service shall follow the same methods and principles set out in the corresponding points of § 5.2.

At least 9 months before the expiry of the Certificate, Kiwa Italia shall start the recertification activities in order to ensure that recertification is completed before the expiry date. If recertification is completed after expiry, from the expiry date of the Certificate until it is renewed, the MDs may no longer be placed on the market with CE marking no. 0476.

After the expiry of the Certificate, if renewal has not been completed within 6 months, Kiwa Italia shall refuse the renewal Application, upload it to Eudamed and inform the Organisation accordingly. The Organisation wishing to regain EU certification shall initiate a new certification process.

Where the Organisation is required to address findings or respond to requests from Kiwa Italia necessary for carrying out recertification activities, Kiwa Italia may interrupt the timeframes of the activities described below up to a maximum of 3 times[30] in total, both for recertification of product certificates and QMS certificates.

In the case of findings classified as critical or major, recertification shall not proceed until their closure has been verified.

Once the recertification process has been successfully completed and the certificates renewed, Kiwa Italia shall plan, within the same year, a surveillance audit in order to comply with the requirement set out in Annex IX, Chapter I, Point 3.3 of the MDR concerning periodic activities every 12 months.

The performance of recertification activities is subject to the regular payment of previous activities by the Organisation; otherwise, Kiwa Italia reserves the right not to carry out the activities required for certificate renewal and to proceed with refusal of the recertification Application as described above.

5.6.2 Recertification of product certificates (EU technical documentation certificates – Annex IX, Chapter 2)

The Organisation shall submit to Kiwa Italia the Application for recertification (signed recertification Quotation), including the following data/documents for each MD already certified for which the recertification Application has been submitted:

a) a list of changes, including both those already notified and those yet to be notified, including those relating to requirements for device components or for the scientific or regulatory context; the list of non-notified changes is required in order to: i) ensure that the device complies with new regulatory requirements or new Common Specifications, ii) take into account new scientific results and new standards, including harmonised standards referred to in point f) below, and changes in medical, scientific and technical knowledge, such as: new treatments, changes in testing methods, new scientific findings on materials and components, including aspects related to biocompatibility, experience derived from studies on similar devices, data from registers and records, and experience derived from clinical investigations on similar devices;

b) the most recent PSUR and a summary of FSCA (field safety corrective actions) based on experience gained through post-market surveillance;

c) a summary of changes to the risk evaluation that have resulted in a different benefit-risk ratio of the MD, including those related to FSCA, adopted on the basis of experience derived from risk management activities;

d) identification of changes made to the device to take into account the state of the art, based on experience derived from updating the demonstration of conformity with the General Safety and Performance Requirements (GSPRs) set out in Annex I of the MDR;

e) the most recent clinical evaluation report (CER), based on experience derived from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF;

f) identification of changes to applied harmonised standards or new standards, to Common Specifications (CS) or to equivalent documents.

Where non-notified changes are required on the basis of new scientific results, the Manufacturer shall indicate in this list whether such basis is represented by:

- new medical, scientific and technical knowledge, such as new medical practices;
- new or updated test methods relating to the properties and performance of the device;

[30] The number of interruptions indicated applies to the conformity assessment procedures for which an Application has been submitted from 25 November 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.

- scientific findings on materials, including their physical, chemical and microbiological characteristics and their biocompatibility;
- results of clinical investigations or performance evaluations on equivalent devices and publicly available data from registers and records.

Once the above documentation has been received, Kiwa Italia shall confirm in writing whether it is complete or whether additional information is required. Any request for additional information shall be limited to what is necessary to complete this evaluation phase.

The assessment of the above data and documents is carried out by Kiwa Italia off-site.

The management of findings resulting from the analysis of the above data and documents shall be carried out as described in § 5.3.4 *Initial assessment of technical documentation*, with the exception of the submission of the revised technical documentation in full, which shall not exceed 3 months from the recording of the findings and in any case within a timeframe that allows Kiwa Italia to complete the recertification activities.

Following the positive completion of the document assessment, including the management of findings, Kiwa Italia shall perform the final review according to the same methods and principles set out in § 5.3.5.

Kiwa Italia shall carry out the document assessment and the final review within a maximum timeframe of 90 Calendar Days[31] for each MD covered by the Application, starting from the date of the email by which the Organisation submitted the complete documentation relating to the individual MD (as confirmed by Kiwa Italia) and ending on the date of completion of the final review.

5.6.3 Recertification of QMS certificates (EU QMS certificates – Annex IX Chapters I and III, Annex XI Part A)

The Organisation shall submit to Kiwa Italia the Application for recertification (signed recertification Quotation) for the ranges of MDs for which the certificate is to be renewed. Kiwa Italia verifies:

a) that all relevant requirements[32] for conducting audits have been fully assessed at least once after the date of certificate issuance and before the expiry date;

b) that the results of all surveillance activities[33] carried out, whether announced or unannounced, during the certification cycle, and in particular on-site audits at the Manufacturer, its critical suppliers, product testing activities, as well as the results of technical documentation assessments carried out on a sampling basis, continue to comply with the requirements of the MDR;

c) whether the audit programme and sampling plan established are still up to date or require updating;

d) that all identified non-conformities have been resolved, or that an appropriate and accepted plan of corrective and preventive actions has been implemented with relevant timelines;

e) where the certification is subject to specific conditions or limitations, whether these are still valid or have become obsolete and require updating;

f) whether the scope of the Certificate needs to be updated.

Kiwa Italia shall request from the Organisation any additional information relating to the above, where necessary; such requests shall be limited to the information required to complete this evaluation phase.

The assessment of the above-mentioned data and documents is carried out by Kiwa Italia off-site.

Following the above document assessment, in the event of a negative outcome, Kiwa Italia shall determine the consequent actions, depending on the findings identified; such actions may include, for example, requests for additional objective evidence, further information or supplementary assessments.

The Organisation shall submit the requested evidence to Kiwa Italia no later than 3 months from the date of the request and in any case within a timeframe allowing Kiwa Italia to complete the recertification activities.

In the event of a positive outcome, Kiwa Italia shall perform the final review in accordance with the same methods and principles set out in § 5.3.5.

[31] This timeframe applies to the conformity assessment procedures for which an Application has been submitted from 25 November 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.
[32] Requirements set out in Section 4.5.2 of Annex VII and in Sections 2.2 and 2.3 of Annex IX of the MDR.
[33] In accordance with Annex VII, Section 4.10 of the MDR.

Kiwa Italia shall carry out the document review and the final review within a maximum timeframe of 90 Calendar Days[34] starting from the date of receipt of the complete recertification Application and ending on the date of completion of the final review.

5.6.4 Decision on recertification

Kiwa Italia applies the same methods and principles set out for the decision on initial certification in § 5.3.6; however, this activity is limited to the information and documents specified in the previous paragraphs relating to recertification.

Where, during the recertification decision activity, Kiwa Italia requires additional information or documents, it shall request them from the Organisation; such requests shall be limited to the information necessary to complete this evaluation phase.

The reissuance of each Certificate and its upload to the Eudamed database shall take place within a maximum period of 20 Calendar Days[35] calculated from the day following the date of completion of the final review relating to the product Certificate and/or the quality management system Certificate. By way of derogation from this rule, where the decision on renewal of the Certificate is taken more than 3 months before the expiry date of the Certificate, the maximum period of 20 days shall start 3 months before the expiry date of that Certificate.

5.7 Other conformity assessment procedures

Importers and distributors carrying out the activities referred to in Article 16, point 2 of the MDR shall submit an Application for certification of the QMS to Kiwa Italia as provided for in § 5.2.

Kiwa Italia shall directly perform the certification audit and the related activities as provided for in §§ 5.3.1, 5.3.2 and 5.3.3, limiting the assessment to aspects of the QMS with reference to the existence of procedures ensuring:

- accurate and updated translation of the information provided with the MD;
- that activities for providing all information necessary for placing the MD on the market and for modifications to the outer packaging are carried out using means and conditions that preserve the original state of the MD;
- that the packaging is not defective, of poor quality or inadequately finished;
- that the manufacturer of the MD continuously informs about any corrective actions adopted to ensure the conformity of the MD;
- that the MD, its packaging or an accompanying document includes information relating to the activity carried out, together with the company name, trade name or registered trademark, the registered office and the address at which the entity can be contacted.

The activities for maintenance and renewal of certification shall follow the provisions set out in § 5.4 and § 5.6, for the applicable parts, and shall be aimed at assessing the aspects described above.

5.8 Supplementary assessments

In addition to all cases already described in the previous paragraphs, Kiwa Italia reserves the right to carry out further supplementary assessments (both documentary and on-site audits) in the following cases:

- for the reasons indicated in the *Kiwa Regulation for Certification*;
- for requests arising during the Certification Decision phase;
- in the event of receipt of information regarding serious incidents, emergencies or malfunctions;
- in the event of receipt of reports or information concerning non-conforming aspects related to certified MDs.

Supplementary audits may also be conducted with short notice (5 Working Days from the scheduled audit date); in such cases, given the impossibility for the Organisation to object to the members of the audit team appointed by Kiwa Italia, particular attention shall be paid to their selection.

Supplementary assessments do not replace or modify the process and frequency of periodic surveillance assessments and shall be communicated in advance to the Organisation.

[34] This timeframe applies to the conformity assessment procedures for which an Application has been submitted from 25 November 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.
[35] This timeframe applies to the conformity assessment procedures for which an Application has been submitted from 25 November 2027 (ref. Implementing Regulation (EU) 2026/977), unless otherwise contractually agreed in writing with Kiwa Italia.

The costs of supplementary assessments are to be considered additional and shall be charged to the Organisation in accordance with the contractual provisions.

In the event that the Organisation is not available to carry out such activities, Kiwa Italia reserves the right to suspend or withdraw (in cases deemed more serious) the issued certification.

5.9 Limitations or specific conditions

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

Such limitations or specific conditions may include changes to the rules of the standard process described in the previous paragraphs, for example: limitations on the validity of the Certificate, limitations to the intended purpose of a device for certain groups of patients, different frequencies of conformity assessment activities (for example for the evaluation of clinical data), specific post-market clinical follow-up studies in accordance with Annex XIV, Part B of the MDR.

6. VOLUNTARY CHANGE OF NOTIFIED BODY

6.1 General requirements

Where an Organisation intends to change NB, Kiwa Italia always requires the prior execution of a Structured Dialogue.

It is understood that, if the Organisation decides to proceed with the change of NB in favour of Kiwa Italia, it is responsible for signing the Transfer Agreement referred to below and requesting its signature from the outgoing NB before signing the quotation of Kiwa Italia.

6.2 Change of Notified Body for certification transfer

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

For the purpose of voluntary change of NB, the certificates to be taken over shall be valid.

The voluntary change of NB is managed by Kiwa Italia in accordance with Article 58 of Regulation (EU) 2017/745. In particular, Kiwa Italia shall require the Organisation to sign a Transfer Agreement that details the provisions set out in the aforementioned Article and that also provides for the involvement of the outgoing NB. “Transfer Agreement” means the agreement entered into between the parties, attached to the Quotation of Kiwa Italia, which governs the modalities for changing Notified Body.

The procedures for transferring certification from the outgoing NB to Kiwa Italia may include a full conformity assessment process (as described in § 5) or a partial one. These procedures shall be determined by Kiwa Italia depending on various aspects such as the reasons for the change of Notified Body, the criticality and number of products, the adequacy and completeness of the information relating to the conformity assessment activities performed by the outgoing NB, etc., and are always agreed with the Organisation during the quotation phase.

The Organisation intending to change NB shall submit a formal Application to Kiwa Italia. In addition to the documentation required in § 5.2, Kiwa Italia also requires the following additional documents:

1. completion of the “Ann. MDR-Change of NB” included in the MOD PO 09 MED_MDR;
2. copies of the complete audit reports for initial certification (or latest recertification) and the latest surveillance audit report carried out by the outgoing NB;
3. copies of the complete document assessment reports for initial certification (or latest recertification) and latest surveillance, including assessments of clinical and post-market data (including PSUR, PMCF, PSR and SSCP) for all certified products;
4. results of external consultations;
5. any documentation demonstrating the management (treatment, corrective actions) of recorded findings;
6. any notes issued during the certification decision phase requiring actions to be implemented by the Organisation;
7. complaints received, vigilance data and evidence of their management;
8. audit programme and sampling plan of the outgoing Notified Body;
9. copies of EU Certificates issued by the outgoing NB;

10. declaration of validity of the certificates issued by the outgoing Notified Body (absence of suspensions or other critical situations affecting certificate validity);
11. copies of quality management system certificates or EU Certificates (where available) of critical suppliers;
12. labelling of products certified by the outgoing Notified Body and draft of the new labelling;
13. declarations of conformity for products certified by the outgoing Notified Body and draft of the new declaration.

Where Kiwa Italia decides to accept the Application for change of Notified Body, it shall assume responsibility for EU certification as of the transfer date (Transfer Date).

Completion of the certification transfer activity (issuance of the Certificate) may take place only once Kiwa Italia is certain that the previous EU Certificate has been withdrawn, based on receipt of communication from the outgoing NB regarding the withdrawal of the existing EU Certificate.

The Organisation shall inform Kiwa Italia regarding the last batches marked with the number of the outgoing Notified Body and placed on the market during the "Transition Period" defined in the Transfer Agreement.

6.3 Change of ON for transfer of the Application for certification

Only Organisations benefiting from the transitional period in accordance with MDR Article 120 (3) may transfer to Kiwa Italia the MDR Application for certification they have with another ON and, where applicable, also the related appropriate surveillance activities. Otherwise, the Organisation shall terminate the contract with the previous ON and apply for initial certification with Kiwa Italia (§ 5.2).

The MDR Application signed with the outgoing ON is governed by the terms of the agreement in force between the Customer and the outgoing ON until the day preceding the Transfer Date, i.e. the date defined in the relevant Transfer Agreement, from which the Application with the outgoing ON is no longer valid and the Application signed with Kiwa Italia becomes effective (therefore the validity of the contract between ON and Customer begins). In particular, the MDR Application submitted by the Customer to Kiwa Italia is subject to the terms of the agreement entered into with Kiwa Italia, which enters into force at 00:00 (time zone of the incoming ON) on the Transfer Date.

The procedures for transferring the Application for certification from the outgoing ON to Kiwa Italia require a full conformity assessment process (as described in § 5).

The Organisation intending to change ON shall submit a formal request to Kiwa Italia as indicated in § 5.2. In addition to the documentation required in § 5.2, Kiwa Italia also requires the following additional documents:

1. reference to the MDR contract signed with the outgoing ON relating to the products subject to transfer, together with the dates of submission of the Application and approval of the contract, or a confirmation letter from the outgoing ON containing equivalent information;
2. declaration by the Organisation regarding the status of progress of the conformity assessment activities performed by the outgoing ON and confirmation of the absence of situations that would have led to refusal of the Application by the outgoing ON;
3. results of external consultations, if carried out by the regulatory authority or the Expert Panel.

Kiwa Italia requires the Organisation to sign a Transfer Agreement that also provides for the involvement of the outgoing ON. After signing the Transfer Agreement, Kiwa Italia also requires the following documents:

- communication from the outgoing ON regarding the status of progress of the conformity assessment activities performed;
- declaration from the outgoing ON that there are no non-conformity situations that could lead to refusal of the Application;
- copy of the initial audit report (Stage 1 and Stage 2), if already carried out by the outgoing ON;
- copy of the complete document assessment reports, including evaluation of clinical and post-market data, including PSUR, PMCF, PSR and SSCP, if already carried out by the outgoing ON.

7. ACTIVITIES FOLLOWING CHANGES IN THE DESIGNATION OF OTHER NOTIFIED BODIES

In accordance with Article 46 of Regulation 2017/745, three situations are distinguished:

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

Where Kiwa Italia receives and accepts an Application for certification for products certified by NBs subject to cases 1 and 3, the activity shall be managed as a new certification and shall therefore follow the process described in the previous paragraphs.

Where Kiwa Italia receives and accepts an Application for temporary assumption of the functions of an NB, with reference to certificates issued by an NB subject to the measures referred to in point 2 above, Kiwa Italia does not issue any Certificate but temporarily takes over the surveillance and monitoring activities relating to the certificates issued by the other NB, assuming their responsibilities. In such cases, the instructions provided by the responsible Competent Authority shall be followed.

Applications relating to cases 2 and 3 shall be acceptable only if the responsible Competent Authority has formally confirmed that the certificates have not been unduly issued and that there are no issues relating to the safety of the MDs.

Where Kiwa Italia decides to accept an Application for certification as referred to in cases 1 or 3, it shall assume responsibility for EU certification:

- immediately in the case of withdrawal of the designation of the previous NB, but the assessment process shall be completed within 12 months from the withdrawal of designation;
- upon completion of the full assessment of the devices, in the event of cessation of activity of the outgoing NB; such completion shall take place within 9 months from the cessation of activity of the outgoing NB.

In the event of cessation or withdrawal of the activity of the outgoing NB, communication from the outgoing NB confirming termination of the contract, including the exact date of cessation of activity, shall be provided by the Organisation.

In the case of limitation or suspension of the designation of the other NB, communication from the Competent Authority shall be provided by the Organisation.

8. SUSPENSION, WITHDRAWAL OR REDUCTION OF CERTIFICATION

Certification may be suspended, withdrawn or reduced for the reasons already stated in this Regulation, in the *Kiwa Regulation for Certification*, upon request of the Organisation, or in the following additional cases:

- presence of serious reports from the market and/or from Competent Authorities, or failure to promptly inform Kiwa Italia regarding actions, of any kind, taken by public authorities and/or incidents or ongoing legal proceedings;
- implementation of changes subject to notification or approval without prior notification to or approval by Kiwa Italia;
- references to certification or use of the CE marking 0476 of Kiwa Italia in a manner not compliant with the provisions of this Regulation;
- incorrect qualification or classification of MDs;
- bankruptcy or cessation of activity of the Organisation;
- cessation of activity or withdrawal of designation of Kiwa Italia;
- limitation or suspension of the designation of Kiwa Italia in cases established by the Competent Authority.

In the event of suspension/withdrawal/reduction, Kiwa Italia shall notify the Organisation in writing, also indicating the conditions to be fulfilled.

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

- request the Organisation to recall products already placed on the market;
- in cases of suspension: allow the Organisation to continue placing on the market products already manufactured and released at the date of suspension, for a period of 6 months from the date of suspension, subject to receipt of a communication signed by the Legal Representative indicating the batches of products in stock; in such cases, Kiwa Italia reserves the right to perform a supplementary audit at the Organisation before granting the possibility to continue placing the products on the market;

- in cases of withdrawal or reduction, the Organisation shall communicate the last batch sold at the time of withdrawal or reduction. Products in stock bearing marking no. 0476 may no longer be sold.

During the suspension period, the Organisation loses the right to refer to certification, to use the CE marking 0476 and the related Certificate; it shall also cease use of all advertising material containing such references and, upon request of Kiwa Italia, return any certification documents.

The conditions for reinstatement of suspended certification (including any required supplementary assessment activities) shall be established by Kiwa Italia based on the reasons leading to suspension and its duration.

Except in exceptional cases (in any case approved by Kiwa Italia or by the Competent Authority), the suspension period shall not exceed 6 months.

Where the Organisation fails to implement the actions required by Kiwa Italia for reinstatement of suspended certification, the certification shall be withdrawn or, where possible, its scope shall be reduced.

Reduction of the scope of certification results in revision of the Certificate, specifying the product types for which certification remains valid. The contract between the Organisation and Kiwa Italia shall cease to have effect with regard to the parts excluded from the scope due to the reduction, while remaining valid and effective for the parts for which certification continues to apply.

Withdrawal of the Certificate entails automatic termination pursuant to Article 1456 of the Italian Civil Code of the agreement to which this Regulation applies, without prejudice in any case to compensation for any damages suffered by Kiwa Italia.

Following withdrawal of certification, the Organisation loses the right to refer to certification and to use the CE marking 0476 and the related Certificate. This right shall also cease to apply with respect to any parts of the certificate affected by a reduction. The Organisation may initiate a new certification process by submitting a new Application.

Suspension, withdrawal or any reduction of the Certificate shall be communicated by Kiwa Italia to the Competent Authority through upload to Eudamed, including information on the reasons and on the MDs affected by the actions.

Kiwa Italia reserves the right to communicate measures of suspension, reduction or withdrawal to third parties upon request.

9. USE OF CERTIFICATION, CERTIFICATE AND CE MARKING

The Organisation shall use the CE marking as defined in Art. 20 and in Annex V of Regulation (EU) 2017/745. In addition, the CE marking is subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Use of the CE marking 0476 is incorrect where:

- the marking is affixed to devices not certified by Kiwa Italia;
- the Certificate issued by Kiwa Italia has expired and has not yet been renewed;
- the devices relate to a certification that has been withdrawn, suspended or reduced;
- the Organisation has not implemented the changes required by Kiwa Italia.

With regard to the correct use of the Certificate and references to certification, in addition to what is indicated in the *Kiwa Regulation for Certification*, the following rules shall apply.

Use of certification or of the Certificate is considered incorrect where it may mislead or cause misinterpretation by a third party regarding the nature, quality or origin of the device. In particular, it shall be clearly evident that certification relates exclusively to the certified product. Partial copies of the Certificate are not permitted.

Where incorrect use of certification, the Certificate or the CE marking is identified, Kiwa Italia shall withdraw the certification and notify the Competent Authority. In more serious cases (e.g. improper marking, fraudulent use), Kiwa Italia shall also inform the Public Prosecutor's Office

10. COMPLAINTS AND APPEALS

10.1 Complaints

The Organisation may submit a documented complaint concerning its interactions related to certification activities with Kiwa Italia.

Such complaint may arise from issues encountered during the certification process, such as delays in carrying out the various phases and/or improper conduct by personnel performing conformity assessment activities on behalf of Kiwa Italia.

Complaints shall be submitted in written form (any medium is accepted) and shall describe in detail the situation that is the subject of the complaint.

Kiwa Italia shall record the complaints, analyse them and inform the complainant of the actions taken within thirty Calendar Days from the date of receipt of the complaint.

To ensure impartiality, all complaints are handled by personnel not involved in the activities to which the complaints relate.

Kiwa Italia shall agree with the complainant whether and to what extent the content of the complaint and its resolution shall be made public.

Further details are available on the website www.kiwa.it (under the *"segnalazioni e suggerimenti"* "reports and suggestions" section).

10.2 Appeals

If the complainant party is not satisfied with the response received or intends to contest a decision of Kiwa Italia, an appeal may be submitted in writing.

The appellant party shall state the reasons for the appeal and, where the appeal refers to a decision of Kiwa Italia, it shall be submitted within 10 Calendar Days from the date of communication of the decision.

Kiwa Italia shall provide the appellant party with a written response and shall notify any actions to be taken within 30 Working Days from the date of receipt of the appeal.

Further details are available on the website www.kiwa.it (under the "*segnalazioni e suggerimenti*" "reports and suggestions" section).

11. UNILATERAL AMENDMENT OF THE CONTRACT

Kiwa Italia reserves the right to amend this Regulation at any time. Any new clauses or amendments shall become effective from the moment they are communicated in writing to the Organisation.

The Organisation that does not intend to accept such amendments may withdraw from the contract by providing written notice via registered letter with return receipt or certified email within 30 Calendar Days, under penalty of forfeiture, from the day following the communication to Kiwa Italia.

The withdrawal shall take effect on the last Working Day of the month in which the communication from the Organisation is received.

12. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT

Kiwa Italia may freely withdraw from this contract by providing written notice to the Organisation with a notice period of 6 months prior to the effective date of withdrawal. Withdrawal by Kiwa Italia entails the withdrawal of the issued certification. The Organisation shall in any case remain obliged to pay Kiwa Italia the amounts due for the services provided during the notice period, as established in the most recent valid Quotation.

If the Organisation intends to withdraw from the contract, unilateral withdrawal during the validity period of the certification shall comply with the notice periods set out in the *General Terms and Conditions* and in *the Kiwa Regulation for Certification*. In particular, for notice periods shorter than 3 months prior to the scheduled audit and longer than 2 weeks, the Organisation shall pay 50% of the amount corresponding to the subsequent activity provided for under the contract. For notice periods shorter than 2 weeks, the provisions set out in the *General Terms and Conditions* shall apply.

The request for withdrawal shall be submitted in writing to Kiwa Italia, on the Organisation's letterhead, bearing the stamp and signature of the legal representative of the Organisation, and shall be sent to Kiwa Italia by certified email or registered letter with return receipt.

Kiwa Italia shall issue an invoice for the costs related to the closure of the certification process, in accordance with the most recent valid Quotation.