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Information Package *Certification of Medical Devices*



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Information Package *Certification of Medical Devices*

Colophon

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1 The purpose of this document

The purpose of this information package is to inform the applicants of Kiwa Dare B.V. about its provision of services, in particular its Notified Body (NB) activities and about certification of Quality Management Systems in accordance with EN-ISO 13485.

1.1 Relevant information

The information that is provided in this package is relevant to the implementation of certification projects with regard to the Medical Device Regulation 2017/745 (MDR) and / or EN-ISO 13485.

As such Kiwa urges the applicant to read this information thoroughly and abide to the processes laid down in this document. Might there be any questions or uncertainties, do not hesitate to contact us via our email address: nbofficedare@kiwa.com¹.

¹ nbofficedare@kiwa.com can be used interchangeably with nl.nobo-office.kiwa.dare@kiwa.com. Information sent to both addresses is handled in the same way and is received by the same team.

2 About Kiwa Dare B.V.

2.1 Who is Kiwa Dare?

Kiwa Dare B.V. (hereafter called Kiwa) is an independent operating company under Kiwa Nederland B.V.

Within Kiwa Dare B.V., a number of activities are performed as provided in below Table.

Activity	Accreditation / Certification	Designations
Measuring, Testing and Calibrations <i>Calibration of electronic measuring equipment and testing, measurements and assessment</i>	ISO/IEC 17025: L279 ISO/IEC 17025: K063 ISO/IEC 17065: C447	NB EMC
Medical Certifications <i>Notified Body (NB) Certification Assessment Body (CAB)</i>	ISO/IEC 17021-1: C637	NB MDD and MDR (NB 1912)

For market approval of hardware medical devices both Product safety and Electromagnetic compatibility (EMC) testing (EN-IEC 60601-1) must be performed under accreditation. These tests can be performed at the accredited test laboratories of Kiwa Dare B.V. or at any other accredited laboratory.

2.2 Scope for accreditation and designation

Kiwa Dare B.V. is designated to conduct conformity assessments on active medical devices according to Annex IX, X, XI part A and XI part B of the Medical Device Regulation 2017/745 (MDR).

The types of conformity assessment are provided in below Table:

Conformity assessment route	Explanation
Annex IX	Conformity assessment based on a quality management system and on assessment of technical documentation
Annex X	Conformity Assessment based on type examination
Annex XI part A	Conformity Assessment based on product conformity verification, production quality assurance
Annex XI part B	Conformity Assessment based on product conformity verification, product verification

Kiwa Dare B.V. performs its certifications (EN-ISO 13485 certification) under accreditation, recognized by the use of the logo of the Dutch Accreditation Council (RvA), RvA C637, on all relevant documents.

The registration of Kiwa Dare B.V. can be found at the site of the Dutch Accreditation Council: <https://www.rva.nl/en/alle-geaccrediteerden/>, and in the Nando database of the European Commission: <https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies>.

Kiwa Dare B.V. is identified as a Notified Body (NB) by the Notified Body number NB 1912.

2.2.1 Notified body scope of Kiwa Dare B.V.

The current scope of designation of Kiwa Dare B.V. is limited to active non-implantable medical devices and non-ionising medical devices.

The types of conformity assessment routes are Annex IX, Annex X, Annex XI part A and Annex XI part B.

The assessments involve medical devices with risk classification: Class I (sterile and/or measuring), Class IIa, Class IIb and Class III for the following product categories provided in below Table:

Code	Product category
MDA 0202	Active non-implantable imaging devices utilising non-ionizing radiation
MDA 0203	Active non-implantable devices for monitoring of vital physiological parameters
MDA 0204	Other active non-implantable devices for monitoring and/or diagnosis
MDA 0302	Active non-implantable devices utilising non-ionizing radiation
MDA 0303	Active non-implantable devices utilising hyperthermia / hypothermia
MDA 0305	Active non-implantable devices stimulation or inhibition
MDA 0306	Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemopheresis (limited to devices for administration and removal of substances)
MDA 0307	Active non-implantable respiratory devices (excluding inhalation anaesthesia devices, lung ventilators and heart-lung machines)
MDA 0308	Active non-implantable devices for wound and skin care
MDA 0309	Active non-implantable ophthalmologic devices
MDA 0310	Active non-implantable devices for ear, nose and throat
MDA 0311	Active non-implantable dental devices
MDA 0312	Other active non-implantable surgical devices
MDA 0313	Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport
MDA 0315	Software
MDA 0316	Medical gas supply systems and parts thereof
MDA 0318	Other active non-implantable devices
MDS 1004	Devices which are also machinery as defined in point (a) of the second paragraph of article 2 of Directive 2006/42/EC
MDS 1005	Devices in sterile condition
MDS 1009	Devices incorporating software / utilising software / controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices
MDS 1010	Devices with a measuring function
MDS 1011	Devices in systems of procedure packs
MDS 1012	Products without an intended medical purpose listed in Annex XVI of Regulation (EU) 2017/745
MDT 2001	Metal processing
MDT 2002	Plastic processing
MDT 2008	Clean room production
MDT 2010	Manufacture or processing of electronic components incl. communication devices
MDT 2011	Packaging, incl. labelling
MDT 2012	Installation, refurbishment

2.3 EN-ISO 13485 Scope

The accreditation scope of Kiwa Dare B.V. is related to Active (non-implantable) medical devices:

- General active medical devices
- Devices for imaging
- Monitoring devices
- Devices for radiation therapy and thermotherapy
- Active (non-implantable) medical devices other than specified

2.4 Impartiality statement

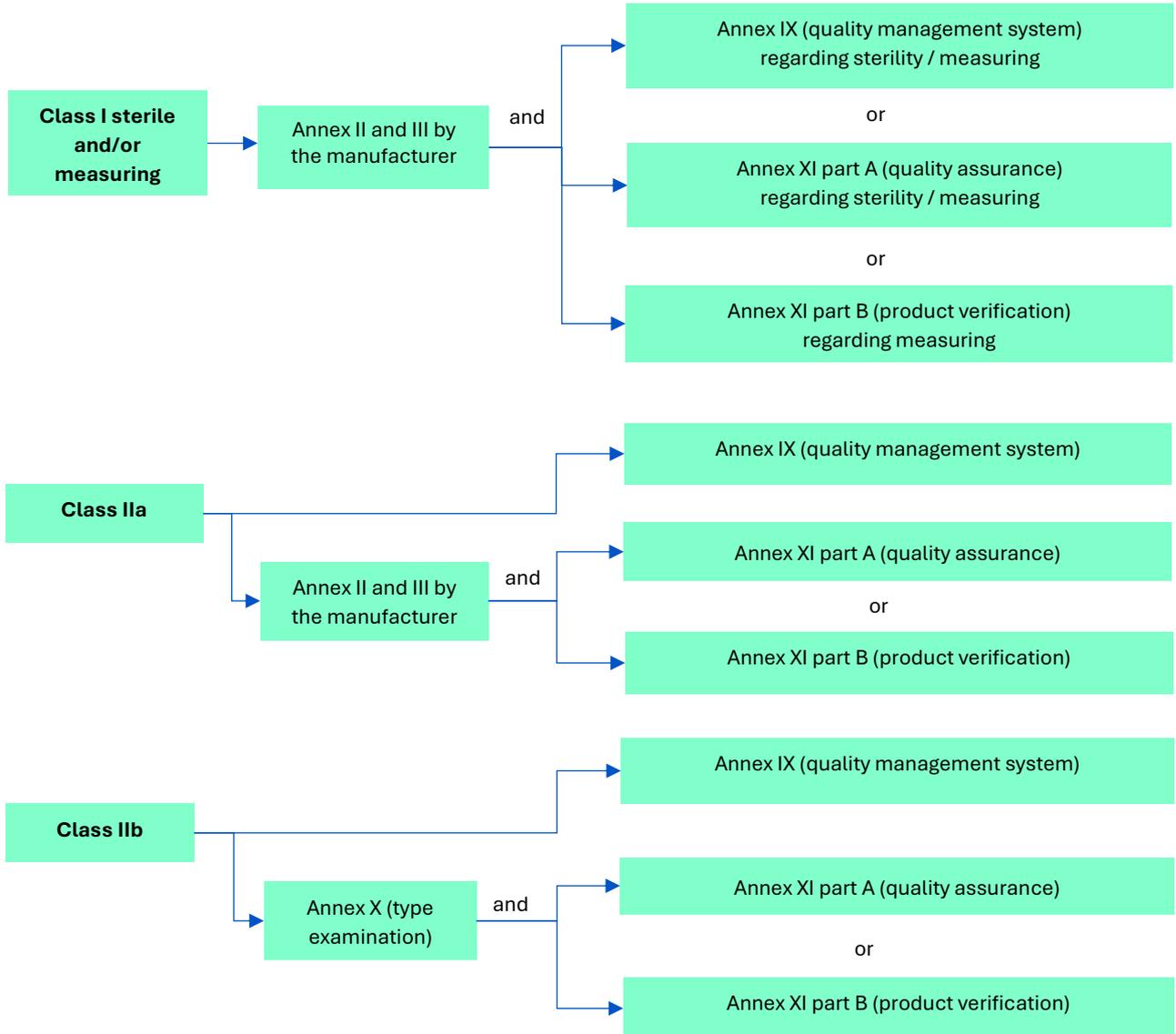
The mission of Kiwa is to support our customers to bring safe products on the market. At the same time, we value impartiality and independence. Our team of skilled auditors, product reviewers and other staff are dedicated to deliver a high-quality service in the field of medical device certification, as well as in quality management system certification.

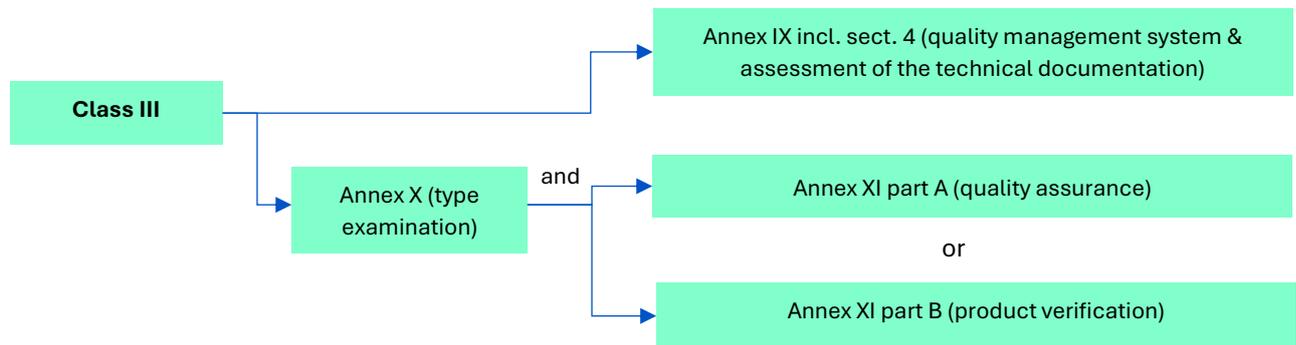
The Management of Kiwa aims for the highest standards with regard to impartiality and independence including the prevention of conflicts of interests. This is achieved by setting high standards for our employees, in close concert with an ongoing risk analysis.

In doing business with Kiwa, our customers can be assured that the certification process is objective and handled in an impartial and independent way, free from internal and/or external pressures. Remuneration of employees is not linked to the outcome of certification activities. Kiwa is an independent operational company realising its profit completely with services to customers. For declarations of impartiality of top management, refer to our website: <https://www.dare.eu/notified-body-medical-devices>.

3 General information on the certification of medical devices

Medical devices that are placed on the market in Europe (European Economic Area) fall under the Medical Device Regulation 2017/745 (MDR). Depending on the risks associated with a device, it can be placed on the market under self-certification (in which case no NB is involved), or a conformity assessment procedure with a NB. A few conformity assessment routes are available to prove conformity of a medical device with the MDR. The Figures below show the different possibilities and the services Kiwa can offer.





Class I medical devices with a measuring function (and/or sterile) are self-certified by the manufacturer according to Annex IX, but a NB is needed to assess the reuse and/or sterility and/or measuring function. Kiwa Dare B.V. can issue an NB-certificate for this class of devices.

Annex IX is the conformity assessment procedure assessing the quality management system and (a sample of) technical documentations falling under the scope of the quality management system. The quality management system is audited to determine the level of conformity and (a sample of) the technical documentations are assessed. The technical documentations are sampled to cover all five years of the Annex IX certificate.

Annex X encompasses a type-examination. During a type-examination, the technical documentation (TD) concerning the product will be assessed by the NB and one or more samples (the 'type') will be inspected and where necessary additionally tested to determine whether the product meets the General Safety and Performance Requirements of the MDR. The required product safety and EMC tests and assessments have to be conducted separately, for instance at Kiwa Dare B.V. (Measurements).

Annex XI part A is the product conformity verification conformity assessment by assessing the production quality assurance. The quality management system is audited to determine the level of conformity.

Annex XI part B is the product conformity verification conformity assessment by means of product verification. In this procedure, a NB inspects and tests all products in order to verify whether these are identical to the type and the technical documentation.

4 The certification process

4.1 Overview



Prior to the start of the certification process, a pre-application needs to be submitted to Kiwa Dare. The applicant will receive a quotation for this process step. The pre-application form contains information about the organisation, the product(s) and the intended purpose. There is a maximum of two rounds of pre-application reviews. Note that English is the only accepted language for submission.

After the acceptance of the pre-application, the chosen conformity assessment route is clear and the agreement with an indicative price offer for the complete certification cycle is made by Kiwa and send to the applicant.

After acceptance of the agreement by the applicant, the certification project is transferred from sales to the process manager. All documentation for the application review must be submitted to the notified body office (nbofficedare@kiwa.com). After acceptance of documentation, the aim is to perform the application review within 10 weeks.

During the application review the scope is determined and the assessment team is assigned, including external experts when necessary. A conclusion will be drawn if the certification project can be initiated and if the applicant is ready for the coming assessments. There is a maximum of three rounds of application reviews.

The required time for the Audits and TD reviews, including external experts, is calculated in detail.

After the application review assessment is carried out, a report is drawn up and send to the applicant. If external expertise is necessary, the applicant is informed in this phase. In case that the detailed time calculation leads to an adaptation of the indicative price offer, a new quotation is sent.

In case of product verification (Annex XI part B), the applicant receives a quotation based on the test plan of the product verification.

A planning for the technical documentation assessment (not applicable for EN-ISO 13485 certification) and the audits is communicated to the applicant by Kiwa.

The applicant receives the stage 1 audit plan (only for EN-ISO 13485). This enables the applicant to make objections to one or more of the audit team members and to the request for the attendance of an observer. During this audit the documentation of the management system is reviewed, and a few particular items are checked to determine if the organisation is ready for the stage 2 audit.

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The applicant submits missing parts of the Technical Documentation as stated in the application review report. During Technical Documentation assessment the conformity and the completeness of the documentation will be assessed by the product reviewer and internal clinician (not applicable for EN-ISO 13485 certification). There is a maximum of 4 rounds and 6 months to solve outstanding non-conformities and questions.

The applicant receives the stage 1 audit report (only for EN-ISO 13485) with possible areas of concern. These areas of concern will lead to a non-conformity during the stage 2 audit if the applicant has not solved these areas of concern. In addition, the applicant receives the stage 2 EN-ISO 13485 or initial MDR audit plan. Kiwa performs the stage 2 EN-ISO 13485 audit, an initial MDR audit or product verification. A maximum of 6 months is allowed between the stage 1 and stage 2 audit.

The applicant receives the audit or verification report, including the deadline for any found non-conformities. The applicant makes a Corrective Action Plan and/or solves the non-conformities that are reviewed by Kiwa. After approval, the corrections and corrective actions can be implemented (for Annex IX and XI part A and EN-ISO 13485).

The certification process is concluded with a formal certification decision. Certification decisions (positive and negative) are communicated via Eudamed (not for EN-ISO 13485 certification).

4.2 Customer certification planning

For each customer a certification planning ('programme') is created that includes all activities that must be performed in the certification period and which resources are required for these activities. This certification planning is drawn up after the application review and will be maintained from this moment by the project manager. All notified changes, the changes received upon request for the preparation of an audit and new information identified during the audits will be incorporated in the certification planning.

4.3 Audits

Audits are held yearly and consist of 3-year cycles for EN-ISO 13485 and 5-year (or shorter, where appropriate) cycles for 'product audits' for MDR (CE). The first audit is named initial audit and is for EN-ISO 13485 divided in a stage 1 and stage 2 audit. A product audit does not have a stage 1, stage 2 approach. The main purpose of the stage 1 is to provide sufficient evidence to conclude readiness for the stage 2 audit. This evidence shall be provided on a minimum by demonstrating a successful internal audit process, which shall be concluded by management via the management review. The stage 2 audit is the main initial audit and can be combined with an initial product audit, and is used to provide sufficient evidence of compliance against the audit criteria by review of all requirements. To add activities to the scope evidence of implementation shall be demonstrated.

The first audit of the new cycle is named a re-certification audit. This audit is used to verify again all requirements of the audit criteria.

The audit in between are named surveillance audits and are used to verify continued effectiveness and maintenance of the quality management system. The main focus will be on implementation evidence as the requirements are already been verified during initial and re-certification audits. Main focus will be on changes since the last conducted audit.

Other audits can be certification transfer audits, unannounced audits, verification audits, supplier audits, re-assessment of lapsed certification, short notice audits and scope extension audits.

If one of these audits, except unannounced audits, is needed this will be discussed in advance with your project manager.

Overall every audit consists of:

- An opening meeting to get an agreement on the agenda and to notify the customer on the scope of the audit, roles and responsibilities and logistic and safety aspects that can have an influence on the audit agenda.
- An audit of the quality management system, including visits of departments and interviews with key personnel that are involved in the quality management system. The auditing is based on a sampling process of the available information.
- Preparation of the closing meeting. The lead auditor has to prepare the closing meeting. Possibly in collaboration with the audit team, if applicable.
- Closing meeting. During the closing meeting the lead auditor presents all the findings of the audit and the follow-up actions of the findings. The closing meeting is finished when the findings of the audit and the follow-up actions are understood by the customer.

4.4 Actions regarding non-conformities

The organization is requested to present information indicating how the non-conformities are handled and solved. The table below shows the type of action per type of non-conformity.

Type	Action required by customer
Non-conformity	For each non-conformity a corrective action plan (CAPA plan) must be submitted to Kiwa Dare B.V. within <u>thirty (30) days</u> of the audit (i.e., last audit day). The plan shall identify: the analyzed root cause, correction and/or corrective action plan and verification of effectiveness plan.
	<p>A major non-conformity shall be corrected and the objective evidence of the correction and corrective action shall be submitted to Kiwa Dare B.V. within a period of <u>ninety (90) days</u> from the audit.</p> <p>Major</p> <p><i>For each major non-conformity the correction and corrective action must be completed, and the implementation must be approved by Kiwa Dare B.V., before certification can be recommended*.</i></p>
	<p>A minor non-conformity shall be corrected and the objective evidence of the correction and corrective action shall be submitted to Kiwa Dare B.V. within a period of <u>six (6) months</u> from the audit*.</p> <p>Minor</p> <p><i>The effectiveness of the actions taken will be assessed at the next scheduled audit. Unless stated differently, minor non-conformities do prevent positive certification decisions.</i></p>
Observation	<p>An observation is <u>not</u> non-conforming. Observations may but are not required to be followed-up by the customer.</p> <p><i>No formal follow-up by Kiwa Dare B.V. will be taken at subsequent audits. Generally observations do require a rationale why not deemed a non-conformity.</i></p>

* Depending on the nature of the non-conformities, the timelines may be reduced and the closure of the verification of effectiveness may be required.

Prior to initial or continued certification and depending on the number of minor non-conformities, evidence of implemented correction and corrective action (CAPA) plans may be requested for a review or verified during a corrective action audit. Not solving effectively and in time, could lead to delays in certification or suspension of the existing certification.

If Kiwa is not able to verify the implementation of corrections and corrective actions of any major non-conformity within 6 months after the last audit day of stage 2, Kiwa must conduct another stage 2 prior to recommending certification.

Note

For initial Technical Documentation (TD) reviews (before the CE certificate is granted), all non-conformities and questions must be solved within 6 months, no difference between major or minor non-conformities is made. After certification, timelines are as indicated in the table above.

The TD review report indicates which timelines are applicable for solving the non-conformities. A CAPA plan is not required for the non-conformities and questions related to the TD review.

4.5 Definitions major and minor non-conformities

4.5.1 Major non-conformity

The relevant requirement of the standard, regulation (MDR and/or MDD) and quality system has not been met.

The finding is:

- I. failure to fully address applicable requirements and implement an entire process for quality management systems (e.g., failure to have a complaint handling or training system)
- II. failure to implement applicable requirements for quality management systems
- III. failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects
- IV. products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labelling
- V. the existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements
- VI. repeated nonconformities from previous audits

4.5.2 Minor non-conformity

A requirement of the standard, regulation (MDR and/or MDD) and quality system has not been fully met.

The finding is:

- I. Non-systemic; and/or
- II. An isolated occurrence; and/or
- III. Not likely to result in the failure of the quality system; and/or
- IV. Not likely to result in the failure of the performance of the product or service

4.5.3 Observation

An observation is not directly related to a specific requirement of the standard, regulation (MDR and/or MDD) and quality system.

4.6 Certification

4.6.1 *Granting and maintaining the EN-ISO 13485 certification*

Once approved, the applicant receives the issued certificate. The certificate will be provided in an official Union language (English) and is provided digitally. Paper certificates (hard-copies) can be provided upon request, however, digital certificates are leading. After a certificate is issued Kiwa has to be informed of all substantial changes to the organisation. These can affect the certification planning. The validity of the EN-ISO 13485 certificate is three years. A surveillance audit is planned every year after certification decision. After three years a recertification audit is planned.

4.6.2 *Granting and maintaining the CE certification Regulation 2017/745*

Once approved, the applicant receives the issued certificate. After a certificate is issued, Kiwa has to be informed of all substantial changes to the device, the technical documentation and/or the organisation (depending on the type of conformity assessment performed). Changes that might have consequences on the conformity devices or quality system certification need to be assessed. These can affect the certification planning. See also section 6. The validity of the certificate is five years, unless there is a justified need for a shorter validity period. For quality management certification, a surveillance audit is planned every year, including a TD review if applicable. After five years, a recertification audit is planned. Unannounced audits are planned at least every five years (not for EN-ISO 13485 certification). Certificates issued for end product verification (Annex XI part B) do not have a validity date, as these are issued for a single batch of products.

4.6.3 *Refusing certification*

In case that a certification assessment results in non-conformities that are not solved within the agreed time frames, the client is noticed in advance of the expiry of the time frame to send in solutions. In case that the non-conformities are still not solved, certification can be refused, and other Notified Bodies and the Dutch Competent Authority will be informed.

4.6.4 *Expanding or reducing the scope of certification*

The scope of certification can be expanded or reduced for Annex IX, XI part A and EN-ISO 13485 certificates. EN-ISO 13485 certificates can be expanded by adding processes to the scope of certification, such as distribution, installation etc. Annex IX and XI part A certificates can be expanded by adding an additional product group. It is possible that during an audit it is determined that a product group or process is deemed not applicable or not in conformity with the requirements. In this case Kiwa will reduce the scope on the certificate.

4.6.5 *Suspending or restoring certification*

The procedure for suspending certification commences with a cause for suspension. There are several potential reasons for suspension, for example:

- Vigilance notifications and recalls;
- Delay in solving open major non-conformities;
- The certificate and certification markings are not used in the proper way;
- Justified complaints by third parties;
- The requirements of the certification scheme are no longer met;
- Substantial changes without notification;
- Change of ownership or management, without notification;
- Another reason which should indicate that the products are no longer in compliance with the requirements of the certification scheme.

The potential cause will be investigated, and the certificate holder will receive a notification in advance in which he is asked for an explanation. After completing the investigation, a report is prepared based on which Kiwa takes a decision whether or not to suspend the certificate.

The certificate holder shall be informed in writing of the outcome and substantiation of the certification decision, and if the certification is suspended, of the suspension, the reason, the regulations and the deadline. The suspension may continue for a period of six months. After this, if no fitting solution is presented, the certificate will be withdrawn.

Once the certificate has been suspended, the certificate holder must abstain from:

- Misleading claims regarding the certification;
- The use of the certification mark;
- Abstain from bringing products on the market (not for EN-ISO 13485);

If necessary, the certificate holder must ensure recall of products brought on the market in order to implement corrective measures.

Kiwa will monitor compliance with the above. Once the reason for suspension is eliminated, the certificate holder will be informed in writing. After this the procedure for maintaining certification will restart.

4.6.6 *Withdrawing certification*

The certificate may be withdrawn if any of the following conditions are met:

- The certificate holder submits a written request to withdraw the certificate;
- The certification is suspended for a period longer than six months.
- The certificate has become invalid because the customer has transferred to another Notified Body.

If one of these conditions for withdrawing the certification is met, the certificate holder, as well as the Competent Authority and other Notified Bodies, will be informed in writing.

4.7 **Periodic safety update report**

For class IIa, IIb and class III devices, a periodic safety update report (PSUR) needs to be drawn up and kept updated, at least annually for class IIb implantable and class III devices and at least every two years for class IIa. The PSUR updates are part of the Technical Documentation and assessed as part of the (surveillance) audits.

For all class I devices requiring involvement of a Notified Body (i.e., class I sterile and/or measuring), a PMS report is required, but not a PSUR.

In case of class III or implantable devices, the PSUR needs to be uploaded to Eudamed by the applicant, and Kiwa will conduct an assessment of the PSUR which will be placed on Eudamed. A quotation will be drawn up for assessment of the PSUR as soon as it is received by Eudamed. In the absence of (the applicable module of) Eudamed, the PSUR shall be provided to Kiwa. A formal written, duly signed purchase order must be received by Kiwa before the PSUR assessment can commence.

5 Rules for certification marks

5.1 General

The certification marking for MDR conformity assessment consists of a CE-marking combined with a Notified Body number. CE-marking is protected by the European Commission. The additional Notified Body number (NB 1912), demonstrates which Notified Body has conducted the certification evaluation. This in turn shows conformity with the general safety and performance requirements of the Regulation. For MDR conformity assessments, the CE-marking combined with our Notified Body number is considered to be the certification marking.

In case of type examination, the Notified Body number cannot be used, because additional conformity assessment steps (Annex XI part A or part B) need to be completed. The EN-ISO 13485 quality management system certification does not have a certification marking. Instead, in case of a positive EN-ISO 13485 certification decision an EN-ISO 13485 certificate is provided.

The certification marking is only allowed to be used on documents in combination with the logo or name of the certificate holder. Kiwa has at all times the right to check the use of the CE marking and evaluate the use against the rules laid down at this page. The certificate holder is obliged to cooperate with these inspections.

Upon learning that a certification marking is wrongly affixed to a device or a product outside the scope of the MDR, Kiwa will inform the Competent Authority forthwith on taken actions.

5.2 Documentation and marketing

The certificate holder is allowed to use the certification marking in marketing displays. This only applies as long as the material is directly related to the certified product or quality management system (QMS) and scope. Every real and/or potential deception needs to be prevented. This means that it should always be unambiguous which products or QMS's are certified and which are not. For EN-ISO 13485 certification the certificate can be used by clients to show compliance to EN-ISO 13485.

Furthermore, statements on the certified management system shall only include reference to:

- the certified client (e.g. brand or name);
- the type of QMS, namely medical devices and the standard EN-ISO 13485;
- the certification body issuing the certificate, namely Kiwa Dare B.V.

5.3 Misuse of certification markings

Use of the certification markings by persons, companies or institutions that are not certified by Kiwa Dare B.V., will be considered misuse. Furthermore, the use of the certification markings by a certificate holder on other products or QMS's than the certified products or certified QMS will be considered misuse. In addition, erroneous and deceptive use of the certification marking is also considered misuse.

If an MDR certificate is suspended or withdrawn, the certificate holder is not allowed to market certified products nor claim certification in marketing displays. Recall of products already marketed might be necessary.

In case of EN-ISO 13485 certificate withdrawal or expiration, the certificate holder is not allowed to state that the QMS is EN-ISO 13485 certified. The client shall remove all references to the standard "EN-ISO 13485" in combination with "Kiwa Dare B.V." from any public information. With regard to EN-ISO 13485, the client is not allowed to include a statement on product packaging or accompanying information that the product, process or service is certified by this means.

5.4 Types of misuse

In cases of misuse, three situations can be discerned:

- Misuse by a certificate holder;
- Misuse by an aspiring certificate holder (applicant);
- Misuse by a third party.

5.4.1 *Misuse by a certificate holder*

In this case, the certificate holder will be immediately informed on the misuse and ordered to end the misuse. A trial period of a month will be observed. If, after this period, the certificate holder keeps misusing the certification marking, the certification will be suspended. If the certificate holder resumes misusing the certificate marking, the certificate will be withdrawn after 6 months. If the ex-certificate holder still keeps misusing the marking, he will be legally declared in breach and legal proceedings will be instituted.

5.4.2 *Misuse by an aspiring certificate holder*

Misuse of an aspiring certificate holder will mostly consist of pretending by the aspiring certificate holder that the certificate is already granted. The aspiring certificate holder will be ordered to refrain from the misuse. As a sanction, the certification process will be suspended.

5.4.3 *Misuse by a third party*

If a third party that is not a (aspiring) certificate holder misuses the certification markings, he will be ordered in writing to immediately refrain from this. If he does not respond to this in a satisfactory matter within a satisfactory time period, legal proceedings will be instituted.

6 Complaints, vigilance and notification duty

6.1 Handling complaints by the certificate holder

After obtaining the certificate, the certificate holder must maintain a procedure for timely complaint handling in accordance with applicable regulatory requirements. Complaint handling records shall also be maintained and include all actions taken.

6.2 Vigilance (not applicable for EN-ISO 13485 certification)

The certificate holder is obliged to notify the applicable competent authority and Kiwa Dare B.V. in the event of:

- a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88 of the Regulation EU 2017/745;
- b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

An **'incident'** means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect;

A **'serious incident'** is any incident that directly or indirectly led, might have led or might lead to any of the following:

- a) the death of a patient, user or other person or,
- b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health or,
- c) a serious public health threat.

A **'field safety corrective action'** means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market.

The notification to Kiwa Dare B.V. must be submitted **without delay**.

The initial report should be made via telephone to the Medical Certifications team via **(+31) 348 200900**. Following the initial notification, a written copy of the report should be submitted via the email address vigilance@kiwa.com - please indicate "Vigilance" in the subject of the email and mark it as urgent / high importance.

After this notification, the certificate holder must provide Kiwa Dare B.V. with updates on correspondence regarding the incident with the competent authority and any subsequent action(s) that the certificate holder takes to control the incident.

6.3 Notification duty

6.3.1 Pre-certification notification of any relevant change

After the certification agreement has been signed, the relevant changes which might need to be informed to the Notified Body are not solely limited to post-certification. In other words, there might be changes even prior to certification that might impact the to be issued certificate. Also these changes must be informed to Notified Body in a timely manner. These changes can be as simple as an address change, or more impactful such as changes to the product and or its specifications. The changes need to be compared with the topics required for the application stage. If the change is related to one of the topic on that list, Notified body must be informed. This is to be done by updating the change including version control in the application form and provided to the Notified body. This is to be done as soon as possible since some changes might have major impact on the ongoing conformity assessment, e.g., technical review or further steps such as final review and decision making.

6.3.2 Notification of change post-certification

Following issuance of the certificate, Kiwa needs to be kept updated on any planned changes to the product or the quality system, as described below. This includes also changes made to Eudamed. This obligation remains present for the complete duration of the certification.

For conformity assessments to Annex IX and XI, part A, any planned substantial change to the approved quality management system or systems or to the product-range covered should be notified.

Note! For class IIb, rule 12 devices, also modifications to the device itself must always be notified, as they fall under the clinical evaluation consultation procedure.

For conformity assessments to Annex IX section 4 (class III) or Annex X, any planned change, that could affect safety and performance of the device or the conditions prescribed for use of the device, including a limitation of intended purpose, should be notified. During the TD assessment and the period of solving the non-conformities, the manufacturer is only allowed to implement changes to the product where these are related to the non-conformities to be solved. Any other planned change should be notified either before the start of the TD assessment or after all non-conformities have been solved.

For all types of conformity assessment changes in the name of the manufacturer or authorised representative (EAR) or to the address of the manufacturer or authorised representative (EAR), or in legal, commercial, organizational status or ownership of the certificate holder (e.g. manufacturer or EAR) must be notified.

Notification of changes should be done using the email address nbofficedare@kiwa.com. A certification employee will evaluate the change. This could possibly result in an additional assessment and if necessary, in a supplemented certificate. Note that the evaluation of the notification of change and possible subsequent assessment is invoiced based on an hourly rate (with a minimum of 2 hrs, product review rate). In some cases, it is necessary that a new formal application review is done. This is the case when, for annex IX and XI, part A, the scope is expanded with a new generic device group or device subcategory. For Annex IX section 4 and Annex X, this is the case when the intended purpose or conditions of use (except for limitations) are changed.

Changes to Eudamed should be notified using the email address nbofficedare@kiwa.com as well. In case a change to Eudamed may lead to the initiation of a notice of change, that process will be followed.

The applicant is not allowed to implement changes before a new or supplemented certificate is obtained or Kiwa reported back that the change is deemed not substantial.

Note

In case of batch verification under Annex XI part B, it is important to notify Kiwa of any changes in the upcoming batch in a timely manner, so that the change can be assessed and any non-conformities or unclarities can be solved prior to the verification of the new batch.

6.4 Examples of substantial changes that must be notified

6.4.1 Annex IX (excluding section 4) and XI part A

Substantial changes to the QMS include, but are not limited to:

- Addition of a new production location
- Changes to critical suppliers or subcontractors (e.g. new suppliers or subcontractors, changes in manufacturing processes of suppliers or subcontractors)
- Changes in manufacturing processes, facilities or equipment affecting the device's safety or performance (e.g. new manufacturing technology)
- Organizational changes or relevant changes in the structuring of the quality management system
- Changes in sterilization procedures (e.g. different sterilization method)
- Changes in cleanrooms (e.g. addition of new cleanroom)

Substantial and other notifiable changes to the product range include, but are not limited to:

- Addition of a new generic device group or subcategory
- Addition of a new device model
- Change in the intended purpose of a device. Note that changes in intended purpose also cover changes in medical indications, part of the body or type of tissue interacted with, intended user, intended patient population, intended environment for use (e.g. from hospital use to home use) and operating principle
- A change to the Basic UDI-DI of a device. Note that a change of Basic UDI-DI is required when the intended purpose, risk class or essential design and manufacturing characteristics are changed, as per MDCG 2018-1
- Changes to labelling regarding warnings, precautions, indications or contra-indications
- A change in the fourth level EMDN code of a class IIb device

6.4.2 Annex IX section 4 and X

Any planned change, that could affect safety and performance of the device should be notified. Examples are:

- Any change in design (minor or major)
- Changes in software (see next paragraph below)
- Changes in intended purpose (including limitations). Note that changes in intended purpose also cover changes in intended user, intended patient population, intended environment for use (e.g. from hospital use to home use) and intended medical indication.
- Changes in conditions for use (contra-indications, relevant warnings)
- Changes in operating principle (e.g. use of a different energy source)
- Changes in specifications
- Changes in materials
- Changes in labelling (with the exemption of changes for the purpose of clarification, not altering indications for use)
- Changes in sterilization method or sterilization cycle
- Changes in packaging that can affect safety or performance

With regard to Annex IX section 4 or Annex X, some software changes need not be notified, these are changes:

- to correct inadvertent logic error, without posing a safety risk and to bring the system back into specification;
- that only introduces non-therapeutic and/or non-diagnostic features such as printing, faxing, improved image clarity, reporting format or additional language support;
- to the appearance of the user interface with negligible risk of impact on diagnosis or therapy delivered to the patient;
- that disables a feature that does not interact with other features.

Software changes that are considered substantial are, for example:

- Software changes, which impact the control of the device, that may alter the diagnosis or therapy delivered to the patient;
- Alterations in software that modifies an algorithm impacting the diagnosis or the therapy delivered;

- Software changes that impact the way data is read or interpreted by the user, such that the treatment or diagnosis of the patient may be altered when compared to the previous version of the software;
- Software changes that replaces previously required user input to a closed loop decision;
- Addition of a new feature to the software that may change the diagnosis or the therapy delivered to the patient;
- Introduction to or removal of a new alarm function from the software such that a response to the new configuration may change the treatment of the patient in comparison to the previous version of the software;
- Software changes that incorporate a significant change to the operating system on which the software runs.
- If the software is modified to correct an error (for example, a change in algorithm), for which there is a safety risk to the patient if the error is not corrected, this software change may require an evaluation and approval by the NB. In such instances and where the software change is a corrective or preventative action for a recall, consultation with the NB is recommended to determine if the change requires an approval.

In case of doubt, please do not hesitate to contact us on the e-mail address mentioned above.

6.4.3 EN-ISO 13485 certification

All relevant changes to the Quality Management System that might have impact on the certification should be notified. This encompasses, for example:

- change of the name or brand name of the client
- changes in the legal, commercial, organizational status or ownership of the client
- changes in organization and management (e.g. key managerial, decision-making or technical staff)
- changes in the contact address and sites of the client
- changes in the scope of operations under the certified management system (e.g. product types/key technologies)
- major changes to the management system and processes
- changes in critical subcontractors or crucial suppliers

6.5 Complaints to Kiwa and appeals on certification decision

Kiwa performs certification activities with care and according to the four eyes principle, yet mistakes can never be completely excluded. In this unfortunate event, Kiwa has a procedure for handling complaints and appeals. This procedure is not only to be used by clients, but may also be used by any other interested party.

Kiwa defines a complaint as every act from a customer or any third party indicating (directly or indirectly) not to be satisfied with the service provided by Kiwa or with a certified client.

Kiwa defines an appeal as a specific complaint where a customer or third party indicates not to agree with the decision taken in the handling of a complaint or with a certification decision taken by Kiwa Dare.

You can report your complaint to your contact person at Kiwa Dare or send the complaint per email to nbofficedare@kiwa.com.

6.6 Management of extraordinary events and circumstances

In case of extraordinary events and circumstances, such as a pandemic, flood, war etc. the affected certificate holder must inform Kiwa of their current situation. Kiwa must evaluate the impact of the extraordinary event and circumstance on the issued certificate. The audit team will determine whether or not onsite or (partly) remote audits can be performed, based on the current legislation, standards and guidelines.

7 Conditions for the conformity assessment

7.1 Purpose of the assessment

The assessment will be carried out with the aim of CE Marking or with the aim of certification according to EN-ISO 13485 (as applied for by the customer).

7.2 Permission of the applicant

The applicant shall permit that the assessment can be performed independently. If certain assessment activities cannot be conducted, or if the independency of Kiwa cannot be guaranteed, Kiwa can decide not to issue a certificate.

7.3 Preparation by the applicant

With the aim to use the available assessment time as effective as possible, it is important that the applicant is well prepared.

7.3.1 Timelines related to delivery of the required documentation

The required time for a complete conformity assessment depends to a great extent on the complexity of the products and the company to be certified and the maturity of the quality management system with regard to the required standards and regulation.

In general, the duration of the conformity assessment procedure for the Regulation (MDR) usually amounts to a minimal of 12-18 months.

Start of the project: Kiwa starts with a pre-application process. After a positive pre-application, Kiwa will send the information package and the application form. After receiving the signed application form, an agreement and a preliminary price indication for the complete certification process is sent (this indicative price may change after the in-depth application review) leading to an adapted quotation).

Once the signed agreement and quotation is received, the project can start. It is of the utmost importance that the relevant documentation is delivered on time. See section 8 for the acceptance criteria of documentation. Kiwa aims to perform the application review within 10 weeks, audits within 8 weeks and the TD review depends strongly on the required competences. If an external expert is required the lead time is hugely effected, since medical doctors have to perform the review next to their normal work in the clinic. For the assessment of non-conformities, 3-4 weeks are required after receiving the documentation.

This time is based on normal conditions but can take longer in case of a concentration of the workload in a certain period or in case that specific employees or experts are not available in time.

7.3.2 Safety of on-site assessments

In case of on-site assessment and audits, the applicant should ensure that the assessment can be practiced safely and completely. Required personal safety measures must be communicated beforehand by the applicant.

7.4 Liability

It must be understood that there is a risk that products will be damaged during tests. Kiwa does not accept any liability for damage to the product as a result of testing activities.

7.5 Observers

Audits by Kiwa may be witnessed by accreditation bodies (e.g., Raad voor Accreditatie), competent authorities (IGJ) and competent evaluators (for training and qualification purposes). Accreditation bodies may decide to verify an audit onsite as part of its accreditation scheme. Clients are in this situation requested to make all necessary arrangements for the participation of observers.

Kiwa will announce this in advance and strives to reduce the burden for customers to a minimum.

8 Revision table

Version	Issue date	Revision description
1.41	11 Mar 2025	Updated section 4.4 clarified info regarding closure of major and minor NCs and added text that timelines can be subject to change. Added info that no CAPA plans are required for the TD NCs and questions.
1.40	27 Jan 2025	Visual: New Kiwa house style, added colophon, levels of table of content changed to 2 levels, date format to DD mmm YYYY, graphical improvements. Content: changed standalone software to software (code 0315), removed Annex II content and referred to Team NB document for TD. Clarification of timelines in section 4.4. Removed flowchart in section 6.5.
1.39	28 Nov 2024	Addition of section 6.3.1 Pre-certification notification of any relevant change.
1.38	06 Nov 2024	Corrected page numbering, updated certification decisions regarding MDR certificates are communicated via Eudamed, clarification that audit cycles may be shorter than 5-years for MDR, explanation that certificates are provided digitally, in English and that digital certificates are always leading over (requested) hard-copies and addition that also changes to Eudamed shall be notified and clarification that notices of changes (and possible additional work) are invoiced (sections 4.3, 4.6.1 and 6.3).
1.37	17 Oct 2024	Updated with clarification which languages are acceptable for submission according to MDR Annex VII 4.2 (section 4 and Attachment A and B).
1.36	22 Jul 2024	Updated with email address Kiwa Dare B.V., included additional information art. 83(4), update of timelines.
1.35	20 Dec 2023	Added pre-application process, update of deadlines for NCs, removed fee table (published on website).
1.34	11 Oct 2023	Added revision table Removed instruction Attachment A: "As a minimum 80% of the required items of the documentation checklist must be submitted at this stage."
1.33	02 Oct 2023	Revised the definitions of vigilance terminology in section 6 to better align the Regulation 2017/745 and added the designated phone number to call in the event of an incident Rephrased the front disclaimer: This publication may only be reproduced and/or made public in its entirety.
1.32	15 May 2023	Revised the vigilance process by updating the email address to notify vigilance cases and add the instruction to include "Vigilance" in the subject of the email and marking it as high importance
1.31	16 Jan 2023	Updated with the new fees for 2023

Attachment A – Acceptance criteria for submitted documentation

It must be noted that English is the only accepted language for submissions, submitted documentation and other relevant and official communications. The folder structure and documentation checklist (document 2196) needs to be used to submit your documentation for the application review, pre-transfer review or TD review. The documentation checklist should be filled out completely with either a reference to the relevant document and the folder pathway to the document.

In case the document is not referenced a justification must be provided with an indication when the document will be available or why it is not applicable.

The documentation is checked if the files:

- are structured by means of the folder structure
- are available and not corrupted
- allow to search for random keywords
- allow to copy text

For hardware devices, Kiwa cannot accept the documentation if the EMC and Product Safety test reports are not submitted at this stage. It is the minimum requirement to start planning the review, since it can hugely affect the certification planning.

In regards to sending the documentation to us there is no specific medium that must be used, however Kiwa needs to archive the documentation in your dossier so it needs to be downloaded from the designated area. The documentation must be downloadable in one go including the folder structure and not fragmented.

Kiwa advises you to send your documentation encrypted by means of a password that is send to us in a separate email to meet cyber security standards.

Kiwa cannot accept your documentation if it does not meet the abovementioned criteria.

Attachment B – Technical documentation

The technical documentation and all other relevant information need to be delivered in English. The technical documentation needs to be structured, searchable and meeting the requirements of Annex II, Annex III and Annex XIV of the MDR.

More guidance can be found in several MDCG documents available at the website of the European commission (https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en) and in the Team NB “Best Practice Guidance for the Submission of Technical Documentation under MDR” Position Paper available at the website of Team NB (<https://www.team-nb.org/>).

Kiwa cannot accept your documentation if it does not meet the abovementioned criteria.