Document 2008
17 Feb 2026

# Information Package *Certification of Medical Devices*

creating trust *driving progress*

kiwa

**Document 2008**
17 Feb 2026

# Information Package ***Certification of Medical Devices***

## Colophon

| | |
|---|---|
| Title: | Information Package Certification of Medical Devices |
| Document Number: | 2008 |
| Version: | 1.44 |
| Date: | 17 Feb 2026 |

**Kiwa Assurance B.V.**
**Kiwa Medical Certification**
Vijzelmolenlaan 7
3447 GX Woerden
The Netherlands

nl.nboffice@kiwa.com
www.kiwa.com

# Information Package
*Certification of Medical Devices*

kiwa

## Contents


**1 The purpose of this document ..... 4**
1.1 Relevant information ..... 4
**2 About Kiwa Assurance B.V. (Kiwa Medical Certification) ..... 5**
2.1 Who is Kiwa Assurance? ..... 5
2.2 Scope for accreditation and designation ..... 5
2.3 EN-ISO 13485 Scope ..... 7
2.4 Impartiality statement ..... 7
2.5 Top-Level Management Responsibilities ..... 7
**3 General information on the certification of medical devices ..... 8**
**4 The certification process ..... 10**
4.1 Overview ..... 10
4.2 Structured dialogue ..... 12
4.3 Customer certification planning ..... 12
4.4 Audits ..... 12
4.5 Actions regarding non-conformities, observations and questions ..... 14
4.6 Definitions major and minor non-conformities, observations and questions ..... 15
4.7 Certification ..... 16
4.8 Periodic safety update report ..... 17
**5 Rules for certification marks ..... 18**
5.1 General ..... 18
5.2 Documentation and marketing ..... 18
5.3 Misuse of certification markings ..... 18
5.4 Types of misuse ..... 18
**6 Complaints, vigilance and notification duty ..... 20**
6.1 Handling complaints by the certificate holder ..... 20
6.2 Vigilance (not applicable for EN-ISO 13485 certification) ..... 20
6.3 Notification duty ..... 21
6.4 Examples of substantial changes that must be notified ..... 22
6.5 Complaints to Kiwa and appeals on certification decision ..... 25
6.6 Management of extraordinary events and circumstances ..... 25
**7 Conditions for the conformity assessment ..... 26**
7.1 Purpose of the assessment ..... 26
7.2 Permission of the applicant ..... 26
7.3 Preparation by the applicant ..... 26
7.4 Liability ..... 26
7.5 Observers ..... 26
**8 Revision table ..... 27**
**Attachment A – Acceptance criteria for submitted documentation ..... 28**

# 1 The purpose of this document

The purpose of this information package is to inform customers and applicants of Kiwa Assurance B.V. about its provision of services, in particular its Notified Body (NB) and Conformity Assessment Body (CAB) activities and about certification of Medical Devices and 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 customer and applicant to read this information thoroughly and abide by the processes laid down in this document. Might there be any questions or uncertainties, do not hesitate to contact us via our email address: **nl.nboffice@kiwa.com** or visit our website **www.kiwa.com**.

## 2 About Kiwa Assurance B.V. (Kiwa Medical Certification)

### 2.1 Who is Kiwa Assurance?

Kiwa Assurance B.V. (Kiwa Medical Certification; hereafter called Kiwa) is an independent operating company under Kiwa NL Holding B.V. You can find more information on our website: **www.kiwa.com**.

Within Kiwa Assurance B.V., a number of medical device-related activities are performed as provided in below Table.

| **Activity** | Accreditation / Certification | Designations |
|---|---|---|
| Measuring, Testing and Calibrations<br>*Calibration of electronic measuring equipment and testing, measurements and assessment* | ISO/IEC 17025: L279<br>ISO/IEC 17025: K063<br>ISO/IEC 17065: C447 | NB EMC |
| Kiwa Medical Certification<br>*Notified Body (NB)*<br>*Conformity Assessment Body (CAB)* | ISO/IEC 17021-1: C637 | NB MDD and MDR 2017/745 (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 Assurance B.V. or at any other accredited laboratory.

### 2.2 Scope for accreditation and designation

Kiwa Assurance B.V. (Kiwa Medical Certification) is designated 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 Assurance B.V. performs its certifications (EN-ISO 13485 certification) under ISO/IEC 17021-1 accreditation, recognized by the use of the logo of the Dutch Accreditation Council (RvA), with accreditation number C637, on relevant documents.

The registration of Kiwa Assurance 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 Assurance B.V. is identified as a Notified Body (NB) by the Notified Body number NB 1912.

### 2.2.1 Notified body scope of Kiwa Assurance B.V. (Kiwa Medical Certification)

The current scope of designation of Kiwa Assurance 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 extracorporal 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 Assurance B.V. (Kiwa Medical Certification) 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. You can find more information on our website: **www.kiwa.com**.

The Management of Kiwa aims for the highest standards of impartiality and independence, including the prevention of conflicts of interest. This is achieved by setting high standards for our employees, supported by ongoing risk analysis. Our auditors and technical experts meet competence requirements defined by the EU MDR, ISO/IEC 17021-1 and the International Accreditation Forum (IAF) Mandatory Documents (MDs).

In doing business with Kiwa, you 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. Kiwa maintains a documented impartiality policy and performs regular risk analyses, in line with ISO/IEC 17021-1 and IAF MDs). Top management declarations are available on our website: **www.kiwa.com**.

## 2.5 Top-Level Management Responsibilities

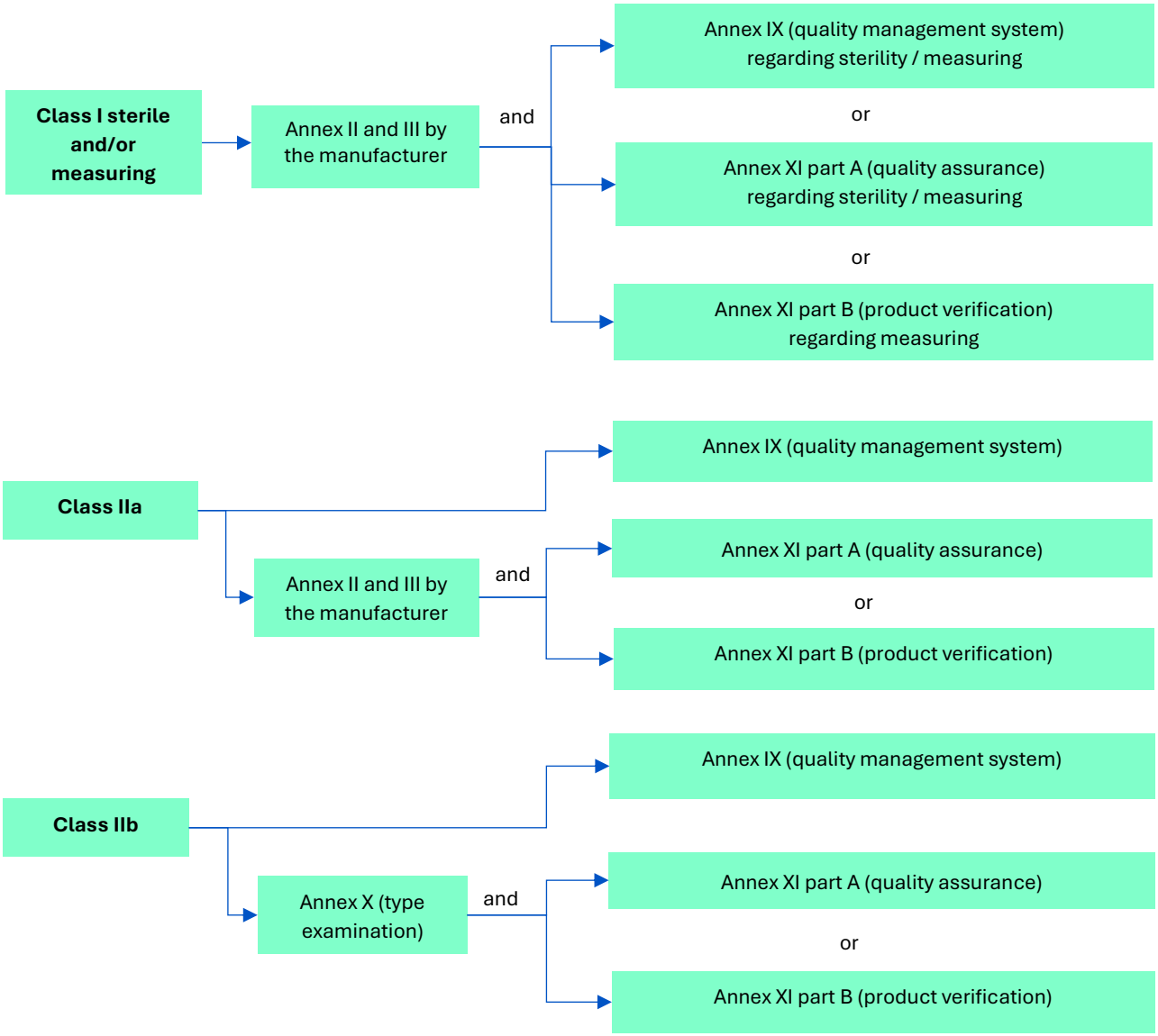
Kiwa Assurance B.V. ensures that its top-level management has defined authority and responsibility for:

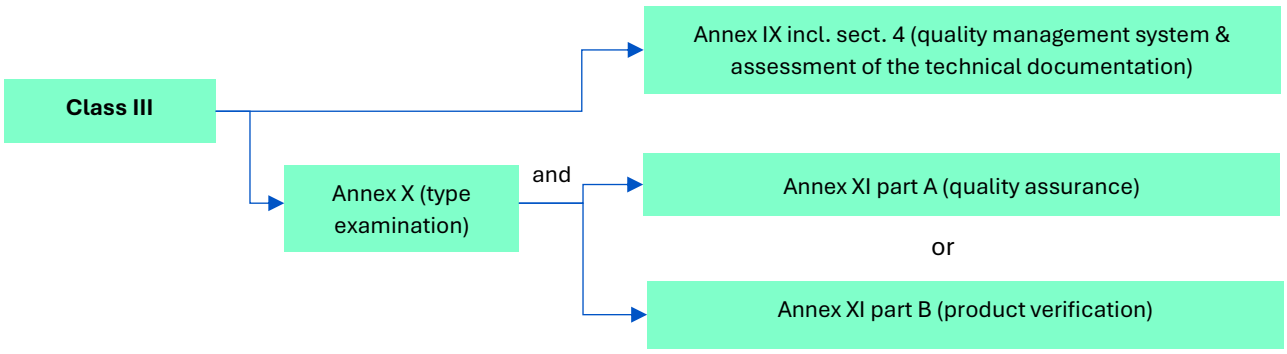
- Provision of adequate resources for conformity assessment activities.
- Development and implementation of procedures and policies for the operation of the notified body.
- Supervision of the quality management system and impartiality safeguards.
- Oversight of financial management related to conformity assessment.
- Certification decisions and contractual agreements.
- Delegation of authority to qualified personnel and committees where necessary.
- Interaction with competent authorities, the European Commission, and other notified bodies.

These responsibilities are documented in our internal governance structure and monitored to ensure compliance with ISO/IEC 17021-1 and MDR Annex VII requirements.

## 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 Assurance B.V. can issue an NB-certificate for this class of devices.

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

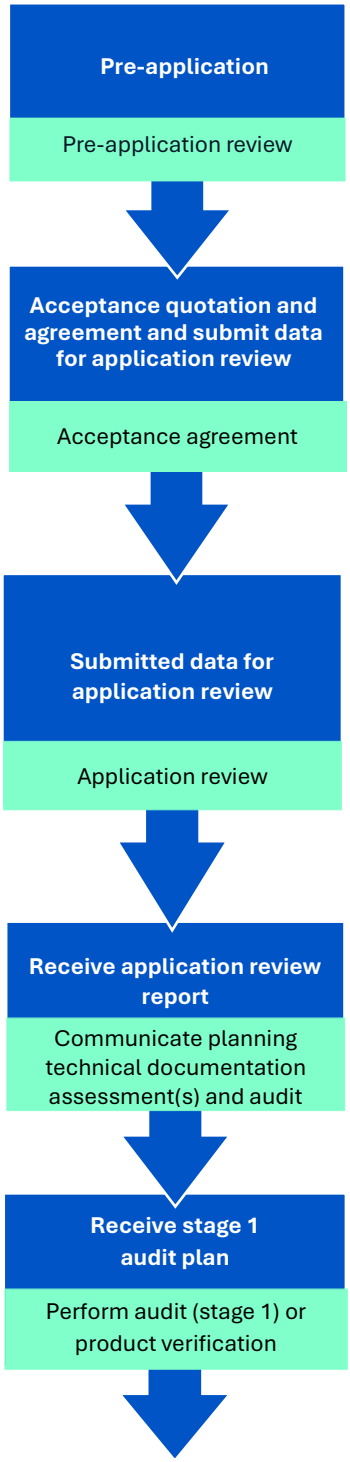
Annex X encompasses a type-examination. During a type-examination, the TD concerning the product will be assessed by the NB and one or more samples (the 'type') will be inspected and where necessary additionally tested to determine whether the product meets the General Safety and Performance Requirements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

Annex XI part A is the product conformity verification conformity assessment by assessing the production quality assurance. The QMS 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 TD.

# 4 The certification process

## 4.1 Overview



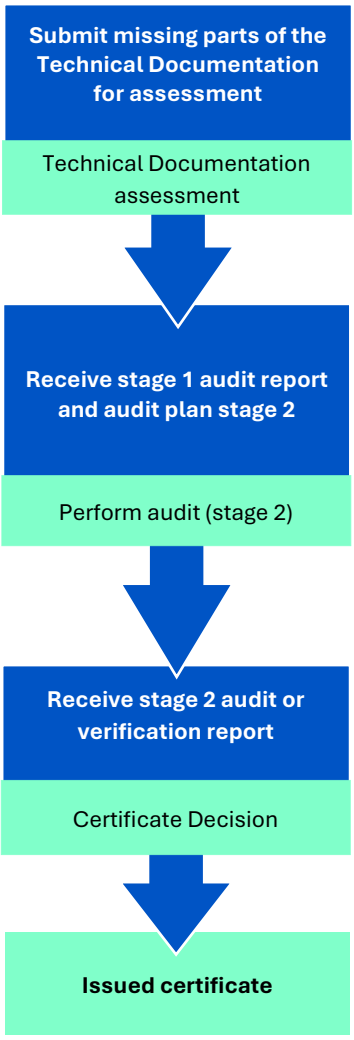

Prior to the start of the certification process, a pre-application needs to be submitted to Kiwa Assurance. The applicant will receive a quotation for this process step. The pre-application form contains information about the organisation, the product(s) and the intended purpose. There is a maximum of 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 sent 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 (nl.nboffice@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. The customer is required to provide the complete set of documentation for the assessment, as stipulated in the documentation checklist. All records must be presented in a clear, organized, readily searchable, and unambiguous manner (MDR, Annex II). This can be effectively accomplished using a Summary Technical Documentation (STED) format. If not, a detailed traceability of requirements to documentation references is required. Failure to comply with MDR Annex II will result in the documentation being rejected. 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 (3) rounds of application reviews (charged against the hourly rate of TD reviewer). The required time for the Audits and TD reviews, including the time for external experts is calculated in detail at the end of the Application review.

After the application review assessment is carried out, a report is drawn up and sent 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.




The applicant submits missing parts of the TD as stated in the application review report. During the TD assessment the conformity 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 four (4) rounds and six (6) months to solve outstanding non-conformities and questions. If unsuccessful, and without any prior agreements to deviate from the aforementioned, the TD assessment will need to be replanned and reevaluated.

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 six (6) months is allowed between the stage 1 and stage 2 audit. For all audits, there is a maximum number of attempts of three (3) rounds for submitting an acceptable CAPA plan. The proposed plan(s), correction(s), corrective action(s) are preferably approved within two (2) rounds. If this is not achieved a meeting will take place to clarify the bottlenecks, leaving one last opportunity to achieve approval. If the third proposed CAPA plan is rejected, a major nonconformity will be issued to aid improving the process of nonconformity handling (CAPA process).

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. Kiwa communicates certification decisions via EUDAMED where applicable (not for EN-ISO 13485 certification).

## 4.2 Structured dialogue

After the pre-application and the application review have been completed, a structured dialogue is scheduled with a dedicated process manager to inform customers about the next process steps and expectations. The aim of this structured dialogue meetings is to smoothen the certification process. Further along the certification process – or earlier – structured dialogue(s) are also possible, taken into account MDCG 2019-6 Rev.5.

## 4.3 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 process 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.

## 4.4 Audits

Audits are conducted annually and consist of a 3-year cycle for certification of the quality management system according to EN-ISO 13485, with annual surveillance audits and a recertification audit before certificate expiry. For CE certification of the product according to the Medical Device Regulation (MDR) 2017/745, a 5-year (or shorter, where appropriate) cycle applies, with ongoing surveillance and at least one unannounced audit during the cycle.

In contrast to the CE scheme with one single initial audit, the quality management system initial audit is subdivided in a stage 1 and stage 2 audit. Stage 1, which generally takes half a day to one day (4-8 hours) audit, evaluates the readiness of the quality management system and accordingly allows to proceed with stage 2 audit. During stage 1, a successful internal audit, approved by management via the management review, is the minimally required criteria to conclude readiness. Stage 2 audit evaluates the quality management system and implementation thereof and aims to find sufficient evidence of compliance against the audit scope and criteria. Subsequently, scope changes (addition of activities) require re-evaluation (via an audit) to evidence sufficient compliance.

The first audit of the new cycle is named a recertification audit. This audit is to verify all requirements according to the audit scope and as depicted by the audit matrix. During the cycle, surveillance audits are performed to verify continued effectiveness and maintenance of the quality management system. Surveillance audits focus on implementation evidence and the potential changes since the last conducted audit.

Transfer audits, verification audits, supplier audits, re-assessment of lapsed certification, short notice audits and scope extension audits are other types of audit that will be conducted as appropriate when applicable and in alignment with the process manager.

Unannounced audits are an integral part of the MDR certification cycle. Kiwa Assurance conducts at least one unannounced audit per five (5) years, in accordance with EU Regulation 2017/745 and Team-NB Code of Conduct. Unannounced audits verify ongoing compliance with MDR requirements, assess production processes, and confirm that devices placed on the market continue to meet safety and performance standards. Additional unannounced audits may be triggered by, not limited to, vigilance issues, complaints, or substantial changes. Unannounced audits are performed without prior notice and may include visits to critical subcontractors.

Shared aspects for all audits are as follows:

- An opening meeting, the agenda and confirmation of the scope of the audit, roles and responsibilities, logistic and any safety aspects that can influence the audit. A signature list is handover to the auditee to track the personnel who were present during the (opening and the closing) audit.
- Conducting audit on the quality management system includes (but not limited to) visits of relevant departments and interviews with responsible personnel and process owners. During the audit, risk-based approach and sampling of the objective evidence is applied.
- Preparation of the closing meeting whereby the lead auditor prepares the closing meeting in collaboration with the audit team. This is done in absence of the auditee.

- Closing meeting during which the lead auditor reconfirms the scope, presents the audit and the follow-up actions. The auditee hand over the signed signature list to the lead auditor to confirm understanding of the audit findings.

### *4.4.1 Audit duration determination*

Kiwa Assurance determines audit duration based on internationally recognized principles (IAF Mandatory Documents and Team-NB Code of Conduct). Audit time is calculated to ensure sufficient depth and coverage for each conformity assessment.

Key factors influencing audit duration include:

- Device Risk Class: Higher-risk devices (Class IIb, III) require more time for review and verification.
- Number of Sites: Multi-site organizations require additional time for sampling and verification.
- Complexity of Processes: Manufacturing technologies, sterilization methods, and software integration affect audit duration.
- Scope of Certification: Broader scopes and multiple product families increase audit time.
- Sampling Approach for Technical Documentation: For MDR , technical documentation is sampled across the certification cycle.

Audit planning is communicated to clients in advance, including the calculated audit time and any adjustments based on complexity or risk.

MDR audits include additional activities in comparison with EN-ISO 13485 audits such as technical documentation review, verification of compliance with General Safety and Performance Requirements, and unannounced audits. These factors generally result in longer audit durations compared to EN-ISO 13485-only audits.

### *4.4.2 Policy on the use of ICT for audits*

Kiwa Assurance B.V. may use Information and Communication Technology (ICT) to conduct parts of audits remotely when appropriate and in compliance with international accreditation requirements. The use of ICT is intended to maintain audit effectiveness while ensuring security and confidentiality.

ICT-based audits are applied only when they do not compromise audit objectives or impartiality. Prior agreement with the client is required before using ICT for any audit activity. Secure platforms and protocols are used to protect sensitive information. The scope, duration, and methodology of ICT-enabled audits follow the same standards as on-site audits.

Clients will be informed in advance about the conditions and technical requirements for ICT-enabled audits.

## 4.5 Actions regarding non-conformities, observations and questions

The organization is requested to present information indicating how 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 **audit** non-conformity a corrective action plan (CAPA plan) must be submitted to Kiwa Assurance B.V. within thirty (30) days 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. |
| | **Major** | A major non-conformity shall be corrected and the objective evidence of the correction and corrective action shall be submitted to Kiwa Assurance B.V. within a period of ninety (90) days from the audit.<br><br>*For each major non-conformity the correction and corrective action must be completed, and the implementation must be approved by Kiwa Assurance B.V., before certification can be recommended. The effectiveness of the actions taken (VoE) will be assessed at the next scheduled audit*.* |
| | **Minor** | A minor non-conformity shall be corrected and the objective evidence of the correction and corrective action shall be submitted to Kiwa Assurance B.V. within a period of six (6) months from the audit*.<br><br>*The effectiveness of the actions taken (VoE) will be assessed at the next scheduled audit. Unless stated differently, minor non-conformities do not necessarily prevent positive certification decisions.* |
| **Observation**** | | An observation is not a non-conformity. Observations may but are not required to be followed-up by the customer.<br><br>*No formal follow-up by Kiwa Assurance B.V. will be taken at subsequent audits. Generally observations do require a rationale why not deemed a non-conformity.* |
| **Question***** | | A question shall be answered and the objective evidence be submitted to Kiwa Assurance B.V. within a period of ninety (90) days from receiving the TD assessment report, unless other arrangements have been made and approved. Each question must be answered, and the implementation must be verified by Kiwa Assurance B.V., before certification can be recommended. |

* Depending on the nature of the non-conformities, the timelines may be reduced and the closure of the verification of effectiveness may be required. In that case, the evidence will need to be provided to the auditor.

** Applicable to Audits only

*** Applicable to Technical Documentation assessment only

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 issued during a stage 2 audit within 6 months after the last audit day of stage 2, Kiwa must conduct another stage 2 prior to recommending certification. For MDR audits, this regards a period of 365 calendar days after the last audit day. Accordingly, an initial audit must be conducted by Kiwa.

**Note**

For initial Technical Documentation (TD) reviews (before the CE certificate is granted), all non-conformities and questions must be solved within a maximum of four (4) rounds and within six (6) months. After certification, timelines are as indicated in the table above (in section 4.5).

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.

## 4.6 Definitions major and minor non-conformities, observations and questions

### *4.6.1 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 non-conformities from previous audits

### *4.6.2 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

### *4.6.3 Observation*

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

### *4.6.4 Question*

Applicable if it is not clear whether or not the requirements are met. For example, a document is missing, or a description in a document is unclear, or there are unclarities because the documentation is not aligned.

## 4.7 Certification

### *4.7.1 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.

### *4.7.2 Granting and maintaining the CE certification Regulation 2017/745*

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. The CE certificates will be uploaded on EUDAMED.

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.

The manufacturer must, at all times, have a valid QMS certificate in place with Kiwa Assurance B.V. or another IAF-accredited body, After five years, a recertification audit is planned. Unannounced audits are planned at least once during the five years cycle (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.

### *4.7.3 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.

### *4.7.4 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.

### *4.7.5 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.

### *4.7.6 Withdrawing certificationtp*

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.

## 4.8 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 TD 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 post-market surveillance (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 for MDR conformity assessment conducted by a Notified Body is identified by a CE-marking combined with a Notified Body number. This Number is unique to the Notified Body which performed the conformity assessment. This in turn shows conformity with the general safety and performance requirements of the Regulation. CE-marking is protected by the European Commission.

Conformity assessment by means of type examination, is without the Notified Body unique number. This is due to the fact that 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 can solely 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 appropriate use of the CE marking and evaluate its misuse against the rules laid down at this page. The certificate holder is obliged to cooperate with these inspections.

Upon learning of an inappropriately affixed certification marking 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 Assurance B.V.

## 5.3 Misuse of certification markings

Use of the certification markings by persons, companies or institutions that are not certified by Kiwa Assurance 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 Assurance 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

For forms and more information, please visit the **customer portal** at our website **www.kiwa.com**

### 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 Assurance 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 Assurance 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.

This should typically consist of the following documentation:

- Copy of the MIR form
- Evidence of notification to relevant competent authorities
- Corrective and preventive actions taken
- FSCA, if applicable
- FSN, if applicable
- Initial investigation report of the vigilance case
- Risk analysis

After this notification, the certificate holder must provide Kiwa Assurance 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. Time needed will be invoiced in blocks of two hours (hourly rate product reviewer).

Please note that Kiwa as the Notified Body will not directly monitor or evaluate the adequacy of the actions from the manufacturer related to the vigilance case, as that is the role of the Competent Authority (art. 89). However, the Notified Body will need to determine if additional actions are required to ensure the ongoing validity of the certificate, such as additional audits. To that end, the Notified Body can request additional information if needed. However, the Notified Body will not issue a report or provide a conclusion on the adequacy of the vigilance investigation of the manufacturer or the follow-up activities of the manufacturer.

## 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 pre-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. Since changes may affect the audit time duration, we recommend to at least inform us three (3) months before the next audit about changes.

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 (AR) or to the address of the manufacturer or authorised representative (AR), or in legal, commercial, organizational status or ownership of the certificate holder (e.g., manufacturer or AR) must be notified.

Notification of changes should be done using the email address **nl.nboffice@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 **nl.nboffice@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 crucial suppliers[1] or critical subcontractors[2] (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;

[1] Providers of essential materials or components that are vital to the manufacturing process but do not perform processes themselves.
[2] Entities performing key manufacturing or service processes that directly affect product conformity.

- 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 crucial suppliers and/or critical subcontractors.

### *6.4.4 Example list of documents to be send with a Notification of Change*

For all notifications of change, make sure to provide:

- An impact analysis of the change
- Updated General Safety and Performance Requirements (GSPR) checklist

In case of device related changes, including addition of devices[3]:

- The device description;
- The intended use description;
- The new Basic UDI-DI, if applicable, or a justification that the Basic UDI-DI is not affected (e.g. addition of a variant with the same intended purpose, risk class and essential design and manufacturing under the same Basic UDI-DI);
- Justification that the device subcategory or generic device group is not affected [4];
- Justification that the risk class is not affected [4];
- Risks analysis, with a clear clarification of additional or new risks, as compared to the certified device
- Clarification if the new device has (or will have) its own MDR Technical Documentation (TD), or is considered a variant under the existing TD;
- Draft Declaration of Conformity (DoC);
- Draft labelling;
- Updated TD [5].

In case of deletion of a device from the certificate:

- Closed DoC, indicating the last released devices under this DoC (e.g., serial numbers, software version)

In case of change of company name or brand name:

- Chamber of Commerce registration;
- Quality Manual;
- Liability insurance;
- Labelling and instructions for use and user manuals;
- Declaration of Conformity;
- Crucial supplier or critical subcontractor agreements.

In case of change of address or addition of a new location:

- Clarification of activities;
- Number of FTEs/shifts;
- Chamber of Commerce registration;
- Moving/transition plan;
- Quality Manual.

In case of a change to key personnel (e.g., CEO / PRRC /Quality Manager):

- CV(s);
- Qualification justification for function(s);
- Role description(s);
- Additional training plans or evidence.

In case of change to or addition of a new crucial supplier or critical subcontractor:

- ISO certificate(s) of supplier;
- QA Agreement;
- Supplier/subcontractor audit report;
- Supplier/subcontractor evaluation;
- Qualification of supplier/subcontractor.

Other changes to the QMS (e.g. scope change, structure, special processes):

- Relevant affected QMS documentation.

[3] In case of only a change of the device name or brand name, only an updated DoC and label needs to be provided.
[4] If this is affected, this will require a complete new application including all documents required as per application procedures.
[5] The updated TD, which might not be finished at the moment of notification of the planned changed, can be submitted after acceptance of the change, but before the change TD review/ sampled TD review/ addition or amendment to the certificate, as applicable.

If the notification of change review is not accepted, then the manufacturer will need to provide additional information (listed in the NoC report). The requested information will need to be provided by the manufacturer to the NB office, and it is also important that the Notification of Change form is also updated with time stamps so it is clear what is the new information.

When the additional documentation and updated NoC form has been received by the manufacturer, then we will perform a second NoC review. If it is still not accepted, then these steps need to be repeated once more until accepted.

After acceptation of the change, it might be necessary to provide a full TD for a surveillance or change TD review. In some cases, it can be necessary to conduct the change review, or addition of a device within the certified device group, before the certificate can be updated.

## 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 Assurance.

You can report your complaint to your contact person at Kiwa Assurance or send the complaint per email to **nl.nboffice@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 or 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 MDR 2017/745 usually amounts to a minimum of 12-18 months.

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 send (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 Attachment A 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 affected, 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., Dutch Accreditation Council; RvA), competent authorities (Dutch Health and Youthcare Inspectorate; 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 |
|---|---|---|
| **1.44** | 17 Feb 2026 | Textual clarifications in chapter 4. Added a list of example documents to be submitted with a notification of change. Incorporated updated requirements from IAF MD4:2025 and added clarifications in section 4.5 regarding NCs for Technical Documentation, including removal of the sentence indicating no distinction between major and minor NCs due to risk of misunderstanding. Added specification that personnel are qualified according to applicable requirements (section 2.4) and added top-level management responsibilities (section 2.5). Updated section 4.4 on UNA, added audit duration determination in section 4.4.1, and added provisions for the use of ICT for audits (MD4) in section 4.4.2. Added definitions of crucial suppliers and critical subcontractors in section 6.4.1. Updated section 7.3.1 to pre-application. Added clarifications in Annex A and updated references to the Kiwa website. |
| **1.43** | 2 Sept 2025 | Addition of section 4.2 structured dialogue. Additional clarification regarding the maximum number of allowed rounds for the technical documentation review. Clarification of section 4.7.2 regarding CE certificates and update of section 6.2 regarding information to be provided in case of an incident. Clarification of section 6.3.2 regarding notification of change. Information of Attachment B incorporated into Attachment A. Clarification of ISO 13485 audit cycle in section 4.4. Addition to the impartiality statement in section 2.4. |
| **1.42** | 01 May 2025 | Update due to name change to Kiwa Assurance B.V. (Kiwa Medical Certification).<br>Update of the required format of technical documentation content provided by the clients.<br>Clarification of the maximum number of NC review rounds for audit and technical documentation assessment process.<br>Clarification of the circumstances which will lead to redoing the initial MDR audit or Technical documentation assessment.<br>Textual update of audit section (no newly added information) |
| **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.<br>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.<br>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 Assurance B.V., included additional information art. 83(4), update of timelines. |

*For older entries, please see previous revisions.*

## Attachment A – Acceptance criteria for submitted documentation

Our approach to technical documentation (TD) assessment is aligned with MDR Annex II and the Team-NB Best Practice Guidance to ensure transparency, fairness and compliance with regulatory requirements. TD files are sampled across the certification cycle to cover all product categories (in case of multiple product categories) and risk classes, provided that the requirements for initial sampling are fully met. Each TD review includes verification of compliance with General Safety and Performance Requirements, including all related topics such as risk management and clinical evaluation.

English is the only accepted language for TD submissions, submitted documentation and other relevant and official communications. The folder structure, forms and checklists provided by Kiwa need to be used to submit your documentation for the (pre-)application review, pre-transfer review or TD review. The documentation checklist should be filled out completely with a reference to the relevant document and section of that document which contains the requested information and the folder pathway to the document.

The technical documentation needs to be structured, fully searchable and meeting the requirements of Annex II, Annex III and Annex XIV of the MDR. For further guidance, manufacturers are encouraged to consult the relevant MDCG documents available on the European Commission's website, as well as the Team-NB publication "Best Practice Guidance for the Submission of Technical Documentation under MDR", accessible via the website https://www.team-nb.org/.

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 provided folder structure
- are identifiable, provided in final version (no drafts), include page numbering and/or chaptering.
- are fully available and not corrupted
- allow to search for random keywords (i.e., please OCR scanned documents to allow for searching)
- 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.

Regarding the submission of documentation, there is no mandatory format or platform required. However, Kiwa must be able to archive the documentation in your dossier, which means it should be downloaded from the designated location. The documentation must be provided as a single downloadable file, maintaining the original folder structure and avoiding fragmentation. To comply with cybersecurity standards, Kiwa strongly recommends encrypting the documentation and sending the password in a separate email.

All documentation needs to be sent to **nl.nboffice@kiwa.com** at least 10 working days before the reserved time slot.

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