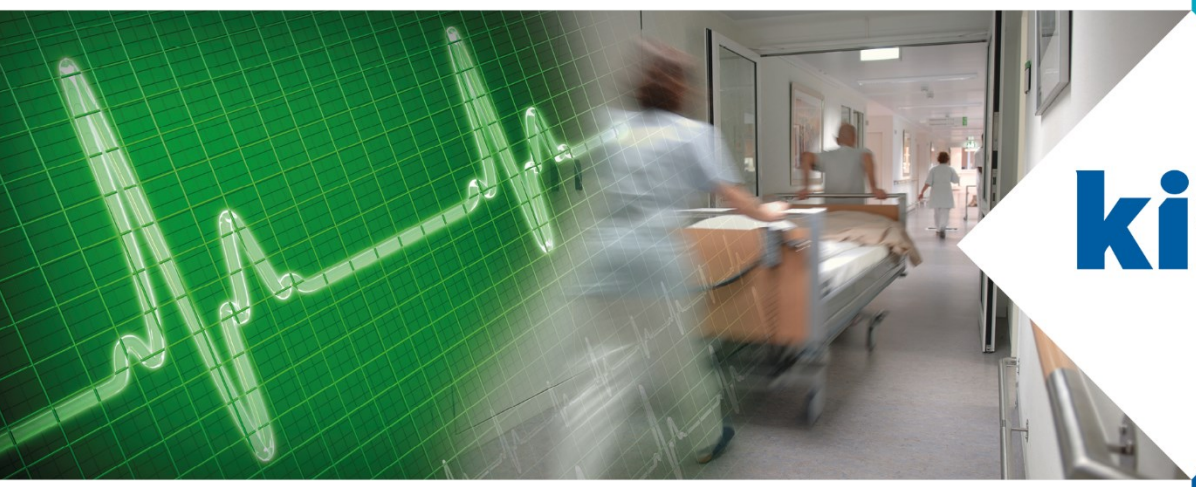
# Information Package Certification of Medical Devices



Trust
Quality
Progress

# Document 2008 (v 1.36)
# Information Package Medical Devices Certification

## Contents

# 1 The purpose of this information package

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.

# 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:

- Calibrations — Calibration of electronic measuring equipment
- Measurements — Testing, measurements and assessments
- **Medical Certifications** — Notified Body / Certification Assessment Body

| ***Activity*** | ***Accreditation / Certification*** | ***Designations*** |
|---|---|---|
| Measuring, Testing and Calibrations | ISO/IEC 17025: L279<br>ISO/IEC 17025: K063<br>ISO/IEC 17065: C447 | NB EMC |
| Medical Certifications | ISO/IEC 17021-1: C637 | NB MDD and MDR (NB 1912) |

For market approval of hardware medical devices both Product safety and 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. (Measurements) 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:

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 are Annex IX, Annex X, Annex XI part A and Annex XI part B. The assessments involve medical devices with safety Class $I_{measure}$, Class $I_{sterile}$, Class $I_{measure\ \&\ sterile}$, Class IIa, Class IIb and Class III for the following product categories:

| 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 protheses, devices for rehabilitation and devices for patient positioning and transport |
| MDA 0315 | Standalone 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

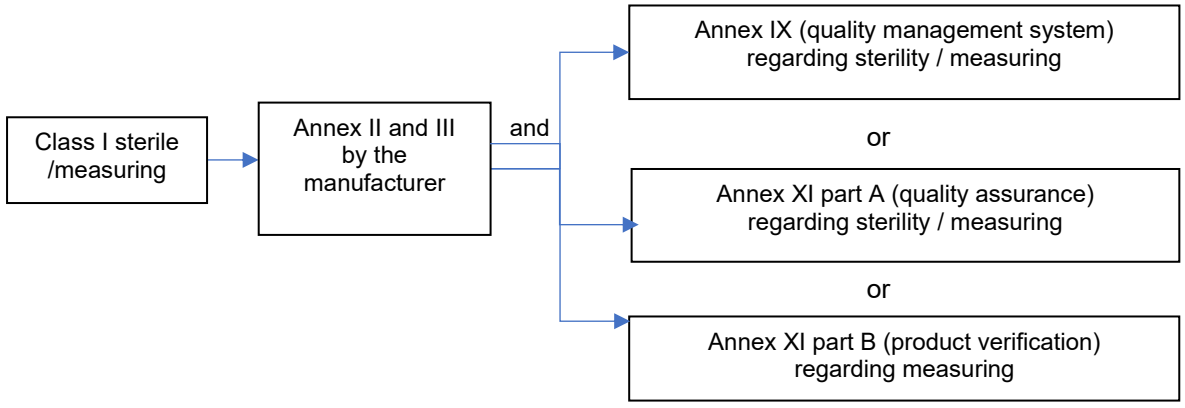
The mission of Kiwa is to support our customers to bring safe products on the market. At the same time, we value impartiality and independence. Our team of skilled auditors, product reviewers and other staff are dedicated to deliver a high-quality service in the field of medical device certification,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

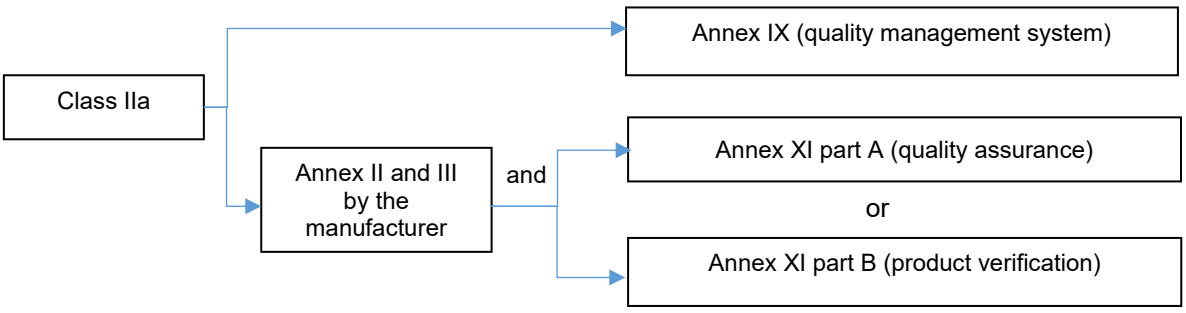
The Management of Kiwa aims for the highest standards with regard to impartiality and independence including the prevention of conflicts of interests. This is achieved by setting high standards for our employees, in close concert with an ongoing risk analysis.

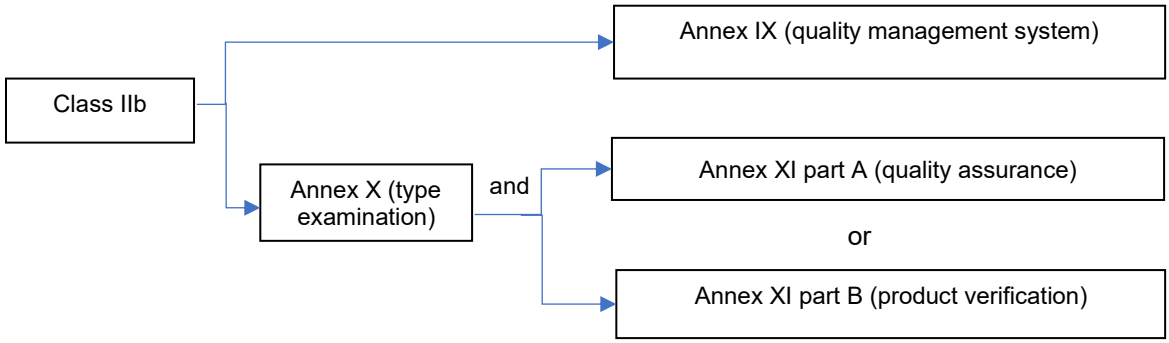
In doing business with Kiwa, our customers can be assured that the certification process is objective and handled in an impartial and independent way, free from internal and/or external pressures. Remuneration of employees is not linked to the outcome of certification activities. Kiwa is an independent 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.

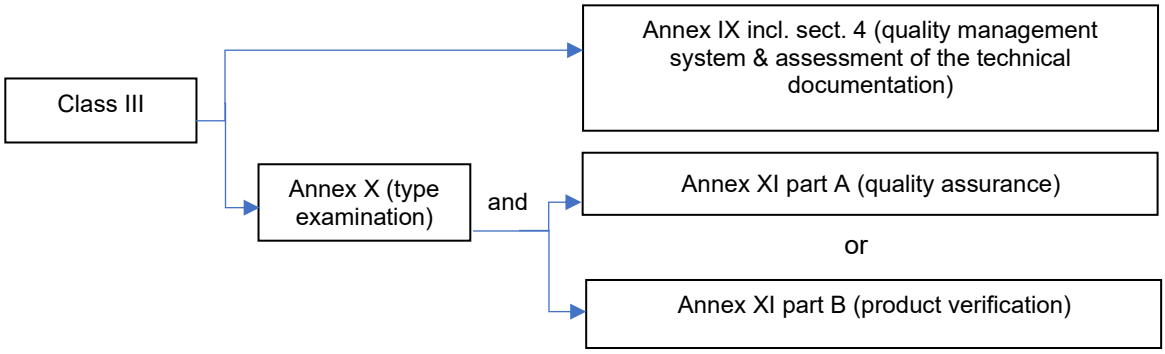
## 3 General information on the certification of medical devices

Medical devices that are placed on the market in Europe (European Economic Area) fall under de 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 and/or reusable) 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 a 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

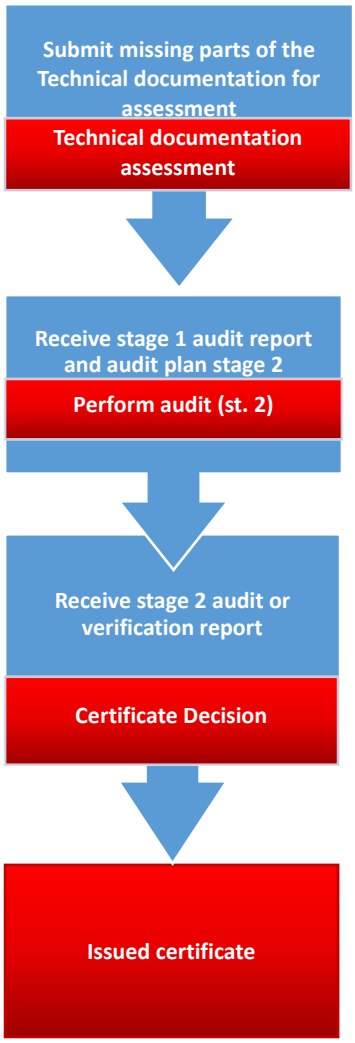

Prior to the start of the certification process, a pre-application needs to be submitted to Kiwa Dare. The applicant will receive a quotation for this process step. The pre-application form contains information about the organisation, the product(s) and the intended use. There is a maximum of two round of pre-application reviews.

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 project 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.




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-ISO13485) 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 to the Competent Authority and other Notified Bodies (not for EN-ISO 13485 certification).

### 4.2 Customer certification planning

For each customer a certification planning 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 cycles for product audits (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 must be submitted to Kiwa Dare 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/or corrective action shall be submitted to Kiwa Dare B.V. within a period of ninety (90) days from the audit, unless other arrangements have been made and approved.<br><br>*For each major non-conformity the correction and corrective action must be completed, and the implementation must be verified by Kiwa Dare B.V., before certification can be recommended.* |
| | **Minor** | The correction and/or corrective action must be completed within a period of 6 months from the audit, unless other arrangements have been made and approved.<br><br>*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.* |
| **Observation** | An observation is not non-conforming. Observations may but are not required to be followed-up by the customer.<br><br>*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.* | |

Depending on the number and severity of the minor non-conformities, evidence of solutions may be asked also for minor non-conformities before initial or continued certification or evidence of solutions of the non-conformities may be verified on-site during a corrective action audit. Not solving effectively and in time, could lead to suspension of the 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 TD reviews, all non-conformities must be solved within 6 months, no difference between major or minor non-conformities is made. The TD review report indicates which timelines are applicable for solving the non-conformities.

## 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. 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 Is, Im, Ir), 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

As soon as the stage 2 audit is concluded, Kiwa needs to be updated on any planned changes to the product or the quality system, as described below. 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 result in an additional assessment and if necessary, in a supplemented certificate. 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.

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 are for example:

- 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 are for example:

- 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.

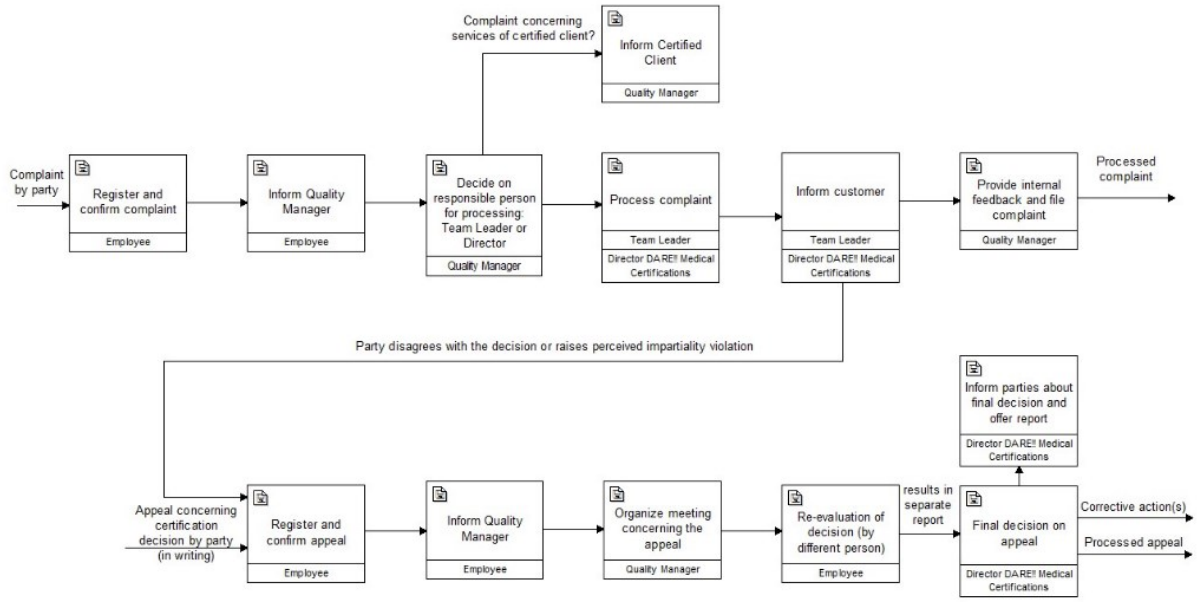
### 6.4.3 EN-ISO 13485 certification

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 also by any other interested parties:



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 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 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 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 upmost 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 nr. | Issue date | Revision description |
|---|---|---|
| 1.36 | 22-07-2024 | Updated with email address Kiwa Dare B.V., included additional information art. 83(4), update of timelines. |
| 1.35 | 20-12-2023 | Added pre-application process, update of deadlines for NCs, removed fee table (published on website). |
| 1.34 | 11-10-2023 | Added revision table<br>Removed instruction Attachment A: “As a minimum 80% of the required items of the documentation checklist must be submitted at this stage.” |
| 1.33 | 02-10-2023 | 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<br>Rephrased the front disclaimer: This publication may only be reproduced and/or made public in its entirety. |
| 1.32 | 15-05-2023 | 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 | 16-01-2023 | Updated with the new fees for 2023 |

## 9 Attachment A – Acceptance criteria for submitted documentation

The folder structure and documentation checklist (2196) needs to be used to submit your documentation for the application review, pretransfer 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.**

## 10 Attachment B - Technical documentation

Below, an outline is given of the required contents of the technical documentation. The technical documentation and all other relevant information need to be delivered in Dutch or English. The technical documentation needs to be structured, searchable and meeting the requirement of Annex II, Annex III and Annex XIV of the MDR. More guidance can be found in several MDCG documents (https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en).

***Description of the product***

- Identification of the product, including Basic UDI-DI
- Operating principles and specifications
- Performance claims
- Clinical benefit(s)
- Intended purpose
- Intended user (incl. requirements to the user, such as training or education)
- Medical indications
- Intended environment of use
- Description of packaging
- Description of product variants, if applicable, and intended combinations with other devices or non-device products
- Classification, including a justification with reference to the classification rules (annex VIII of the MDR)
- A draft Declaration of Conformity

***Overview of general safety and performance requirements, applied standards and common specifications***

The technical documentation should contain an overview of the general safety and performance requirements (GSPR), including a justification for each requirement not deemed applicable. This overview should contain (harmonised) standards and CS that have been used to show compliance to the GSPR, including the used version of the standards. The overview should be accompanied by direct references to documents within the technical documentation where evidence of conformity is present.
With regard to initial certification, in principle it is expected that harmonized standards are used, if available, or if these are not available, the latest EN versions of the standards. In case these are not used, a detailed and thorough justification is expected of this decision and how it is ensured that the same level of compliancy and state-of-the-art is reached.
With regard to products already on the market under a MDR certificate, it is expected that the manufacturer draws up an implementation plan in case a new version of a used standard becomes available. This implementation plan should be finalized within a year. Within three years after first issuance of the new version of the standard, it is expected that the standard is complied with. This will be checked as part of the surveillance activities during the certification cycle.

***Design and construction***

- Technical description, including schematics, print lay-outs, overview of safety critical components and the related datasheets.
- Description of embedded software and software directly required for the use of the device. A description of the software development process, the software development plan, the verification and validation, in principle according to EN-IEC 62304 (and EN-IEC 82304 in case of standalone software).
- Test reports to show conformity of the product with the General Safety and Performance Requirements, for example electrical safety, EMC and biocompatibility test reports. Include the test laboratory and its accreditation for these tests.

- If tests are conducted by the manufacturer or a non-accredited laboratory, a justification how quality is ensured.
- User manual, installation and service manuals, labelling (including a description of location on packaging etc.). Every claim and warning that can be found in the manual, brochures, website etc., needs to be supported by pre-clinical and clinical evidence, risk analysis etc.
- Information on the manufacturing process, its validation, continuous monitoring and final testing.
- Overview of all manufacturing sites, including suppliers and subcontractors, where design and manufacturing activities are performed.

***Biocompatibility***
A biological safety evaluation of materials in contact with the patient should be present. The EN ISO 10993 series are the applicable standards. The biological safety evaluation should clearly indicate which person(s), including competences, conducted the evaluation. The evaluation should be risk-based and make clear which parts of the device are in patient contact and how the device, or parts of it, is categorized according to location of application and duration of application. Repetition in use is an important aspect here, since repetitive use prolongs contact duration, even if a device is reapplied. Based on categorization, it should be evaluated which hazards are relevant. Subsequently, these hazards should be evaluated and required testing should be determined.

***Pre-clinical evaluation***
For bench testing, simulation testing and animal studies, if applicable, a description should be present on the goals, methodology, analysis and results of the tests or studies.
A pre-clinical literature review should be present, describing the clinical background to which the device is situated. Note: this is not the clinical literature evaluation to demonstrate the safety and performance of the device itself (described in the next chapter), but a literature review to embed the device in the current clinical practice, its use, alternatives, state-of-the-art etc.

***Clinical evaluation***
A clinical evaluation should always be conducted. Guidance on how to conduct such an evaluation can be found in several MDCG documents.

A clinical evaluation is necessary to show conformity of the device with the general safety and performance requirements and all performance claims and intended clinical benefits, and to collect information on hazards, risks, possible side-effects and usability. It starts with a clinical literature review. A clinical investigation is required if conformity to the general safety and performance requirements cannot be fully covered by a literature review, based on investigations of equivalent devices. In case of class III, a clinical investigation is almost always required. If the clinical data is in that case based on a clinical investigation of an equivalent device, a contract should be in place with the manufacturer of the equivalent device, allowing ongoing and full access to the TD of that device. In that case, a post-market clinical follow-up is always required. For other classes, if clinical data is based on equivalency, this should be justified in-depth and it should be described and substantiated how access to relevant information from the equivalent device is ensured.

In case of a review of the available literature and data, a signed and dated report with the following information needs to be present:

- Description of the methodology of the literature review (scope, data sources, search strategy, justification that all publications, also the ones with a negative result, are included, exclusion criteria).
- Justification of equivalence of the current device with the devices described in the literature.
- Description how references are weighed for the final conclusion (considering robustness methodology, expertise etc.)
- Analysis and conclusions (Are performance claims, benefits etc. backed up? Is the scope completely covered or is a clinical investigation required for certain aspects?

- Full versions of the selected papers.

If a clinical investigation is necessary, this should in principle have been conducted in conformity with EN ISO 14155 and in conformity with article 62 to 84 of the MDR, as applicable. Please bear in mind that all clinical investigations in human subjects need not only be approved by a METC or other relevant ethical body, but also need to be notified to the competent authority of the country were the study is conducted (IGJ, Dutch Health and Youth Care Inspectorate in the Netherlands).

Again, a signed and dated report with the following information needs to be present:

- Copy of the research protocol as submitted to the ethical commission / competent authority.
- Copy of approval letters.
- Copies of submitted amendments during the investigation.
- Clinical investigation plan with an explanation of amendments to the original approved protocol.
- Copy of the final report (summary, introduction, materials and methods, results, conclusions, risk / benefit assessment), dated and signed by the manufacturer and the principal investigator (of each investigation site, if applicable).
- Appendix with a list of the investigation site and investigators, monitors, statisticians etc. and the declaration of approval of the ethical commission of each site.

In case the clinical evaluation is based on non-clinical data, a full justification meeting the requirements of article 61.10 should be present, including a referral to the non-clinical data supporting safety and performance and an appraisal on how this data is able to show that the device is in conformity with GSPR 1 and 8. This should be documented in a clinical evaluation report.

***Usability***

Usability engineering is an important aspect in the context of safety. Since optimization of usability has a direct impact on the user interface, it is essential to consider usability right from the first steps in designing a medical device, and to document the procedure thoroughly. In case no user interface is present, the accompanying information should still be subjected to the usability process. The process of usability engineering should in principle follow EN ISO 62366.

The basics of this standard, and for usability engineering in general, are the following aspects:

- Identification of hazards that could occur during normal use, including use errors and control of the risks arising from those hazards;
- Verification of user interface requirements; as defined in a usability specification
- Formative and summative validation against criteria specified in a usability validation plan

The hazards and concurring risks are used as input for the risk management process and are analysed accordingly. Those hazards are used as input in establishing verification and validation criteria; requirements and criteria should be defined such that risks are minimized if the user interface conforms those requirements. Any design changes to the user interface are analysed anew for newly occurred hazards and should be verified and validated again. The user interface in usability engineering relates to the total of interactions occurring between user and device.

To determine possible usability-related hazards, the following information needs to be considered (and therefore present in the usability file):

- Use specification (medical indication, user profile etc.)

- Typical frequent use scenario's and worst-case use scenario's (those are also used as input in the validation process, in which representative users could be asked to pass certain typical use scenario's)
- Use errors (also use errors caused by an incorrect mental model that the user could have of the operating principle of the device)

As mentioned before, the hazards found in this process are included in the risk management process. The usability file should contain a reference as to where the usability-related hazards can be found in the risk management file.

Validation should occur according to a predefined validation plan, bases on hazardous use scenarios. The methods used for validation and the criteria against which validation takes places should be documented, as well as how and which representative users are included.

For the whole process of usability engineering, it is important to consider not only actual use, but also user actions related to transport, storage, installation, maintenance and disposal. Therefore, the definition 'users' encompasses not only care personnel, but also installers, transporters, service personnel etc. Instructions for use and other information are also considered as a user interface and should be incorporated in the usability engineering process as well.

***Risk management file***

The EN ISO 14971 is the standard describing the requirements of the risk management process. An important point when using this standard, is that it deviates from the requirements of the Medical Devices Regulation (MDR) itself. The difference is that the standard implies that risk should be reduced to an acceptable level, and when this level is reached, no further reduction is required. The MDR however, states that risks should be reduced until further risk control measures do not lead to a significant reduction of risks, without negatively affecting the risk-benefit ratio.

Therefore, it is important to clearly describe what endpoints are chosen to determine whether a risk cannot be further controlled. This should be based on (harmonized) standards and the state-of-the-art, as known from clinical practice, scientific literature, comparable devices and best medical practice. These endpoints and the sources of information they are based on, should be clearly documented. As opposed to the standard, where only unacceptable risks have to be weighed against the clinical benefit, the MDR requires that all remaining risks should be weighed against the clinical benefits, regardless if they have been reduced to an acceptable level or not. Only risks that are fully controlled until no risk remains, can be exempted from this requirement.

In a risk analysis, there are three important aspects: hazard, severity of harm and probability of occurrence of harm. Hazard is the potentially dangerous situation. Examples are electrical hazards, mechanical hazards, thermal hazard, hazards related to use errors etc. In the risk management file, every potential hazard needs to be clearly described. A hazard can lead to harm. A short description of the harm that can occur due to a certain hazard should be available in the risk management file, as well as a rating of its severity. Not every hazard that is identifiable has to be analysed in the risk analysis. If a hazard is completely eliminated by the design of the device, it is of no use to conduct risk estimation on it. Also, if the severity of harm caused by a hazard is negligible, that hazard could not pose a risk to the user or patient and does not have to be included.

For hazards that are included into the risk analysis, the next step is to determine the probability of harm, since not every hazard leads to harm. The severity of harm combined with the probability of harm leads

to an estimation of the risk. After risk is estimated, risk controls should be implemented. After implementation of risk controls, the risk estimation can be updated to evaluate whether the control has led to a significant reduction of the risk. Also, the risk control measures should be evaluated for new risks. Important here is to realize that a risk estimation or risk matrix in itself is not enough to determine that a risk is acceptable; it is merely a tool to quantify risks before and after risk control measures. For each risk, it should be evaluated, based on endpoints from standards or state-of-the-art, if the risk is reduced. Risk reduction measures should be taken to the point where further implementation of risk controls does not reduce the risk anymore. All remaining risks should then be weighed against the medical benefits, as derived from the clinical evaluation. Risk control measures in itself shall also be further assessed for possible newly introduced hazards.

Important to realize when assessing potential hazards, is that not only failure or faults in the device should be considered, but also, amongst others, hazards related to normal (clinical) use and foreseeable misuse and hazards related to transport, storage, disinfection etc. In this regard, the use of FMEA and related techniques is often too limited for a risk evaluation according to EN ISO 14971. However, FMEA and related techniques can be used to discover hazards induced by failures of the device or manufacturing process. Also, annex C of the EN ISO 14971 gives guidance to this process by supplying a list of questions to be considered when determining potential hazards.

Another important point is that manufacturers that are used to performing FMEA on their manufacturing processes often take probability of detection into account when estimating the proportion of risk. However, for a risk analysis on actual devices during use, this might not always be the best method. Firstly, detection during use will not always lead to prevention from harm, when the person detecting the hazard does not have the ability to prevent harm. Secondly, in many hazards related to use, detection does not play a role. Also, when detection does play a role, probability of occurrence of harm is often directly related to probability of detection; if a certain hazard is detected by the user, the user will take evasive action if possible or refrain from using the device, thereby lowering the probability of harm. For those reasons, including probability of detection directly into risk estimation can lead to odd or unrealistic results, unwantedly raising the magnitude of risks that are improbable but non-detectable or lowering risks that are highly severe and probable but have a high chance of detection. Better options to include probability of detection is by including it directly into the estimation of probability of occurrence of harm (which is quite natural, since a high chance of detection immediately lowers probability of occurrence), by implementing it as a correction factor for detectable risks (excluding it from hazards where detection plays no role) or by using it as a risk reduction measure. When probability of detection is taken into account, it is important to consider whether the detection really leads to prevention of harm: the detection should occur before any harm could have happened and the person to detect should be able to take appropriate action to prevent harm.

Also, one should keep in mind that the use of risk priority numbers (RPN) as often used in FMEA and its variants can be less fitting for risk assessment and evaluation. An RPN is a measure of risk priority, not an evaluation of risk itself. There are often several ways to arrive at the same RPN, while the associated risk is not the same. For example, a hazard with minor harm that will almost always occur can obtain the same RPN as a critical hazard that can occur occasionally. Both risks should be addressed differently however, when applying risk reduction methods and also weighed differently against the medical benefit.

The risk management plan and process should be documented into the technical documentation. Risk management is an ongoing process in which post-production collection of information should be

accounted for and used as input in the risk management process. As mentioned above, a risk analysis should not only take normal use, but also foreseeable misuse into account.

The risk management file should contain the following aspects:

- Management responsibilities (determining risk management policy, policy assignment of personnel to risk assessment).
- Qualifications and records of personnel that conducted the risk analysis.
- Methods of determination and estimation of hazards and risks and method to determine risk acceptability endpoints including a description how resources and state-of-the-art are included in the decision.
- Methods used for the risk / benefit assessment.
- Description of the device, including normal use and reasonably foreseeable misuse.
- Qualitative and quantitative characteristics of the device related to safety and essential performance.
- Identification of hazards.
- Estimation of the risks related to hazards included in the risk analysis.
- Risk control measures taken to reduce risks. Risk control should take these steps in order of priority: first safety by design and if that is not possible, inherent safety measures (alarms etc.) and finally by instruction. If no further risk control by these steps is possible, information and warnings should be provided for the residual risk. Keep in mind that information on residual risk does not lead to further risk reduction.
- Risk control measures should also be reviewed for any new hazards that could arise from implementing them.
- Risks should be reduced as far as possible, until further control measures do not significantly reduce the risk anymore. The risks should be weighed against the medical benefit, both separately and combined with all other remaining risks. The medical benefit should be based on the clinical evaluation.
- A risk – benefit appraisal for each individual risk and for all risks together
- Conditions for safety (e.g. device should only be used by trained personnel, or not used in certain patients) should be documented and also described in the information for the user.
- Measures (design, production, packaging) taken to guarantee optimal performance of the device during its expected service should be documented.
- Information on remaining risks, risk control measures etc. need to be available to the user in the instructions for use and, if necessary, on the labelling.
- The strategy to ensure ongoing collection on post-production information of the device from users and publications on the device or comparable devices should be documented. This information should be used as input in ongoing risk management.

***Post-market surveillance and clinical follow-up***

A post-market surveillance plan needs to be present. This plan should describe a proactive and systematic strategy of collecting of post-market information from clinical use. The depth of the post-market surveillance is dependent on the estimated risks. The collected information should be implemented in the risk analysis, usability file, clinical evaluation etc., and where necessary used to improve the device. The plan should describe how this will be done. In case of death or serious injury of patients or users as a result from using the device, this should be reported immediately to the competent authority and also to Kiwa Dare B.V. In case of non-serious incidents, if their frequency and/or severity increase in a statistically significant way, this should be reported to the authorities via

EUDAMED. For that reason, the PMS plan needs to encompass both an evaluation of the foreseeable severity and frequency during an indicated time period, and a method to determine a significant increase. Also, a procedure for communicating this information via EUDAMED should be present.

A separate PMCF plan as required by Annex XIV, part B of the MDR should be present. Often, it is necessary to conduct a post-market clinical follow-up study. If this is the case, a protocol for this should be described in the technical documentation. If no clinical follow-up is conducted, this should be justified in the technical documentation.
General PMCF activities, such as collecting clinical use data and literature review, are always required. Procedures, goals, methodology and planned analysis of data should be described, including a time schedule and a plan for updating the technical documentation as a result of PMCF findings.

***Summary of safety and clinical performance***
For class III and implantable devices, a summary of safety and clinical performance should be provided. The label and instructions for use should indicate where this can be found. The summary shall be written in a way clear to the intended user, and where relevant to the patient. It shall contain full device identification, a device description, intended purpose, indications, contraindications, risks and side-effects and patient population. Possible diagnostic or therapeutic alternatives should be described. Used harmonized standards and common specifications should be referred to.