Appendix 1: Comparing Australia and Europe

Part 1: Full quality assurance procedure

The conformity assessment procedures set out in this part provide for the manufacturer of a kind of device to implement a quality management system (QMS) for the design, production, packaging, labelling and final inspection of the kind of device.

The equivalent European conformity assessment procedures are in Annex IX of the European Regulations.

Key Differences[1]

The key differences in the European Regulations in comparison with the Australian Regulations are:

1. Emphasis on implementation of the QMS systematically throughout the life cycle of the device.
2. Increase in retention period of documents from 10 to 15 years for Class 4, Class III, and implantable Class IIb medical devices, and an increase from five to 10 years for all other medical devices, after the last device has been placed on the market. This relates to documents such as: Declaration of conformity, QMS documentation, information on QMS/devices changes, technical documentation and notified body decisions and reports.
3. Emphasis on requirement of documentation on a post market surveillance system, including post market clinical follow-up plan or post-market performance follow-up plan (where applicable), clinical evaluation plan or performance evaluation plan, and the relevant procedures to ensure compliance with the obligations resulting from provisions on vigilance[2] detailed below.
    a. In case of serious incident, the reporting timelines specified for a manufacturer and related procedures.
    b. Requirements for manufacturers to report any statistical significant increase in severity of non-serious incidents that could have a significant impact on the benefit risk analysis and the methods used for such determinations.
    c. Procedures around performing investigations of serious incidents and undertaking field safety corrective actions, taking into account the protection of public health.
    d. Requirement for manufacturers to ensure information around field safety corrective action is bought to the attention of the users in the form of field safety notice.
    e. Establishment of the vigilance systems that contains periodic summary reports, report on serious incidents and field safety corrective actions, reports by manufacturers on trends, periodic safety update reports and field safety notices.
4. Requirement for Class I medical devices that are sterile, with a measuring function, or are reusable surgical instruments to have assessment of technical documentation relating to the specialised procedures.

Part 1.6: Design examination

The equivalent European conformity assessment procedures, for the European Regulations are in Chapter II of Annex IX.

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[1] Annex IX, Chapter 1 The Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[2] Article 87 – 92 of EU MDR

Key differences[3]

The key differences in the European Regulations in comparison with the Australian Regulations are:

1. Assessment of technical documentation is applicable to:
    a. Class IIb medical devices (except those devices with a special purpose, being a medical device to which Regulation 3.10 applies).
        i. Class IIb non-implantable medical devices are to include an assessment of design dossier of **at least one representative device per generic device group.**
        ii. Class IIb implantable medical devices (except for sutures, staples, dental filings, dental braces, tooth crowns screws, wedges, plates, wires, pins, clips and connectors), include an assessment of design dossier **for every device**.
    b. Class 2, 3, and 4 IVD medical devices.
        i. Class 2 IVD medical devices will have reviews of technical documentation on a representative basis, with reviews based on 'product categories'.
        ii. Class 3 IVD medical devices will be assessed as kinds of medical devices.
        iii. Class 4 IVD medical devices will have their technical documentation reviewed (no sampling approach).
2. All medical devices are to have technical documentation as per:
    a. Annex II – Technical Documentation.
    b. Annex III – Post market surveillance documentation[4].
3. Detailed procedures for assessment of technical documentation for the devices such as:
    a. Class III and Class IIb active devices that are intended to administer and/or remove medicinal product.
    b. Devices containing a medicinal substance.
    c. Devices containing tissues or cells of animal origin or their derivatives.
    d. Devices containing tissues or cells of human origin or their derivatives.
    e. Devices containing substances or combination of substances that are absorbed by or locally dispersed in the human body.
    f. Self-testing IVD medical devices.
    g. IVD medical devices to be used at point of care.
    h. IVD companion diagnostics.
4. Increase in retention period of documents from 10 to 15 years for Class 4, Class III, and implantable Class IIb medical devices, and an increase from five to 10 years for all other medical devices, after the last device has been placed on the market. This relates to documents such as:

[3] Chapter II, Annex IX, The Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[4] Refer Appendix B and C for detailed technical and post market documentation requirements.

Declaration of conformity, QMS documentation, information on QMS/devices changes, technical documentation and notified body decisions and reports.

Part 2: Type examination

This conformity assessment procedure sets out requirements for manufacturer to arrange for examination of a **representative sample** of a kind of medical device.

The equivalent European conformity assessment procedures are in **Annex X** of the European Regulations.

Key Differences

The key differences in the European Regulations in comparison with the Australian Regulations are:

1. Application to include technical documentations outlined in Annexes II (technical documentation) and Annex III (post-market surveillance documentation)[5].
2. Increase in retention period of documents from 10 to 15 years for Class 4, Class III, and implantable Class IIb medical devices, and an increase from 5 to 10 years for all other medical devices, after the last device has been placed on the market. This relates to documents such as: Declaration of conformity, QMS documentation, information on QMS/devices changes, technical documentation and notified body decisions and reports.

Part 3: Product verification

This procedure sets out requirements for manufacturers to arrange for examination and testing of each device of that kind of representative sample from a batch of medical device of that kind.

The equivalent to this conformity assessment procedure in the European Regulations is Annex XI.

Key Differences:

The key differences in the European Regulations in comparison with the Australian Regulations are:

1. Emphasis on requirement of documentation on a post market surveillance system, including post market clinical follow-up plan or post-market performance follow-up plan (where applicable), clinical evaluation plan or performance evaluation plan, and the relevant procedures to ensure compliance with the obligations resulting from provisions on vigilance detailed below.
    a. In case of serious incident, the reporting timelines specified for a manufacturer and related procedures.
    b. Regulatory body to take appropriate measures such as organising targeted information campaigns to health professionals, users, and patients.
    c. Requirements for manufacturers to report any statistically significant increase in severity of non-serious incidents that could have a significant impact on the benefit risk analysis and the methods used for such determinations.
    d. Procedures around performing investigations of serious incidents and undertaking field safety corrective actions, accounting for the protection of public health.
    e. In case of serious incidents related to substances such as medicinal substance, derivatives of tissues or cells of human origin incorporated in the devices, the relevant competent authority of the substance to be informed of the of the incident and the relevant corrective action.

[5] Refer Appendix 3 and 4 for detailed technical documentation requirements and Appendix 6 for post market documentation requirements.

f. Requirement for manufacturers to ensure information around field safety corrective action to be bought to the attention of the users in the form of field safety notice.

g. Establishment of the vigilance systems that contains periodic summary reports, report on serious incidents and field safety corrective actions, reports by manufacturers on trends, periodic safety update reports and field safety notices.

2. Increase in retention period of documents from 10 to 15 years for Class 4, Class III, and implantable Class IIb medical devices, and an increase from five to 10 years for all other medical devices, after the last device has been placed on the market. This relates to documents such as: Declaration of conformity, QMS documentation, information on QMS/devices changes, technical documentation and notified body decisions and reports.
3. Requirement that the Class IIa medical devices conform to the technical documentation referred to in Annex II and III.
4. Verification of Class 4 IVD medical devices on each manufactured batch of devices, with conclusions of the tests provided to the notified body without delay.

Part 4: Production quality assurance procedure

This conformity assessment procedure sets out requirements to implement a QMS for the production and final inspection of the kind of medical device.

The equivalent to this conformity assessment procedure is provided in Annex XI of the European Regulations.

Key Differences:

The key differences in the European Regulations in comparison with the Australian Regulations are:

1. Emphasis on requirement of documentation on a post market surveillance system, including post market clinical follow-up plan or post-market performance follow-up plan (where applicable), clinical evaluation plan or performance evaluation plan, and the relevant procedures to ensure compliance with the obligations resulting from provisions on vigilance, including:
    a. In case of serious incident, the reporting timelines and related procedures.

    b. Requirements for manufacturers to report any statistically significant increase in severity of non-serious incidents that could have a significant impact on the benefit risk analysis and the methods used for such determinations.

    c. Procedures around performing investigations of serious incidents and undertaking field safety corrective actions, taking into account the protection of public health.

    d. Requirement for manufacturers to ensure information around field safety corrective action to be bought to the attention of the users in the form of field safety notice.

    e. Establishment of the vigilance systems that contains periodic summary reports, report on serious incidents and field safety corrective actions, reports by manufacturers on trends, periodic safety update reports and field safety notices.

2. Requirement for technical documentation referred to in Annex II and III.
3. Increase in retention period of documents from 10 to 15 years for Class 4, Class III, and implantable Class IIb medical devices, and an increase from five to 10 years for all other medical devices, after the last device has been placed on the market. This relates to documents such as:

Declaration of conformity, QMS documentation, information on QMS/devices changes, technical documentation and notified body decisions and reports.

Part 5: Product quality assurance procedure

The European Commission has removed the equivalent Part 5 - Product Quality Assurance Procedure detailed in previous European Medical Device Directives.

Part 6: Declaration of conformity

The equivalent to this conformity assessment procedure is found in Annex IV in the European Regulations.

Our requirements and the European requirements are similar.

Part 7: Procedures for medical devices used for special purpose

This conformity assessment procedure requires manufacturers of a medical device used for a special purpose, such as custom made medical devices and system or procedure packs, to prepare a statement containing information related to the device and prepare and keep up to date particular documentation in relation to the device.

The European equivalent to this conformity assessment procedure is in Annex XIII of the EU MDR; there is no equivalent in the EU IVDR.

Key Differences:

The key differences in the European Regulations in comparison to the Australian Regulations are:

1. All Class III implantable custom devices[6], in addition to Annex XIII procedure will be required to undergo procedure under Annex IX (i.e. Full Quality Assurance Procedure) or Annex XI – Part A (i.e. Production quality assurance procedure).
2. Explicit mention of requirement for indication, if the device contains medicinal substance, or tissues or cells of human origin, or of animal origin.
3. Emphasis on manufacturer to review and document experience gained in post-production phase, including the post-market clinical follow-up plan.
4. Increase in retention period of documents from 10 to 15 years for implantable medical devices, and an increase from five to 10 years for all other medical devices, after the last device has been placed on the market.

Part 8: Clinical evaluation procedures

This conformity assessment procedure requires manufacturers of a medical device to obtain and evaluate clinical data in relation to the device. The equivalent European conformity assessment procedures are Annex XIV Clinical evaluation and post-market follow-up in the EU MDR Regulation and Annex XIII Performance evaluation and post-market follow-up in the EU IVDR Regulation.

We have recently updated guidance to explain our interpretation of our existing Australian Regulations for clinical evidence for medical devices, including IVD medical devices:

- Clinical evidence guidelines: Medical devices
- Clinical evidence guidelines supplement: In vitro diagnostic (IVD) medical devices

[6] **Article 52**(8), The Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

The EU MDR Regulation Annexes XIV (p164) has reinforced requirements for medical devices (non-IVDs) on clinical evidence, including:

- clinical follow-up
- clinical evaluation and investigation
- specified requirements on the content of:
  - clinical evaluation reports
  - clinical evaluation plan
  - post-market clinical follow-up plan
  - post-market clinical follow-up evaluation report.

The EU MDR provides further information in Chapter VI – Clinical evaluation and clinical investigations (Article 61-81).

Similarly, the EU IVDR Regulation, Annex XIII has reinforced requirements for IVD medical devices on performance evaluation, including specified requirements on the content for:

- performance evaluation:
  - performance evaluation plan
  - demonstrating the scientific validity and analytical and clinical performance
  - clinical evidence and performance evaluation report
- clinical performance studies:
  - methods for studies
  - study reports

The EU IVDR provides further information in Chapter VI – Clinical evidence, performance evaluation and performance studies (Articles 56-77).

Key Differences from EU MDR:

The key differences in the EU MDR Regulation in comparison to the Regulations are:

1. Emphasis on requirement of clinical documentation such as clinical evaluation plan, clinical evaluation report and post market clinical follow up plan.
2. Clear details on contents of the clinical evaluation plan, clinical evaluation report and post market clinical follow up plan. Refer to Appendix 5 for more details.
3. For Class III and Class IIb medical devices, consideration for the manufacturer to consult with an external panel regarding the manufacturer's intended clinical development strategy and incorporate the panel's recommendation in the clinical evaluation report.
4. Details the procedure for clinical evaluation to be based on scientific literature, evaluation of clinical investigations and consideration of alternative treatment options.
5. Emphasises that clinical investigations must be conducted on implantable devices and Class III devices, except if:
   a. the device has been designed by modification of an already marketed device by the same manufacturer and there is a sound rationale that this modification will not adversely affect clinical safety and performance.
   b. the modified device has been demonstrated by the manufacturer to be equivalent to a marketed device that has been approved by the notified body, along with the two manufacturers having a contract in place that explicitly allows the manufacturer of the

modified device full access to technical documentation of the equivalent device and original clinical evaluation has been performed on the equivalent device in compliance with requirements of this regulation.

c. the clinical evaluation of the marketed device claimed equivalent is sufficient to demonstrate conformity of the modified device with relevant safety and performance requirements.

d. the device has already been placed on the market on basis of sufficient clinical data and is in compliance with product specific common specifications where available, or

e. devices are sutures, staples, dental filings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which clinical evaluation is based on sufficient clinical data, or

f. Justification in view of well-established technologies similar to those used in exempted Class IIb implantable devices (such as sutures, staples…) or to protect health and safety of patients or other aspects of public health.

6. Clinical evaluation and its documentation shall be updated throughout the lifecycle of the device concerned and for Class III and Class IIb implantable devices, post market clinical follow-up evaluation report shall be updated at least annually.
7. Detailed requirements for:
    a. conduct of clinical investigations to demonstrate conformity of devices that includes considerations for designing and conduct of investigations.
    b. informed consent by the subject for clinical investigation.
    c. considerations when clinical investigations are conducted on minors.
    d. considerations when clinical investigations are conducted on pregnant or breastfeeding women.
    e. considerations when clinical investigations are conducted on incapacitated subjects.
    f. considerations when clinical investigations are conducted in emergency situations and damage compensation that covers any damage suffered by the subject.
    g. considerations for clinical investigations on devices already approved.
8. Detailed requirements around the clinical investigation application and assessment requirements by the member states which include assessment of compliance of investigational device with applicable general safety and performance requirements and risk minimisation to ensure health and safety of the subjects.
9. Details requirements for conduct of clinical investigation, electronic system on clinical investigation, substantial modifications to clinical investigations.
10. Details requirements for recording and reporting of adverse events that occur during clinical investigations.
11. Requirements around information from the sponsor at the end of clinical investigation or in the event of temporary halt or early termination.

Key differences from EU IVDR:

The EU IVDR Annex XIII has specific requirements for IVD medical devices which are modified, or additional, to the Part 8 conformity assessment procedure requirements, including:

1. To plan, continuously conduct and document a performance evaluation by which data are assessed and analysed to demonstrate the scientific validity, analytical performance and clinical performance of that device for its intended purpose, as stated by the manufacturer.
2. Specific requirements for information to be included in a performance evaluation plan, including:
    a. demonstrating scientific validity.
    b. demonstrating analytical performance.
    c. demonstration of the clinical performance, includes:
        i. an additional option for using “published experience gained by routine diagnostic testing”.
        ii. that clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data.
        iii. that clinical performance shall be demonstrated and documented in a clinical performance report.
3. Clinical evidence and its assessment is to be **updated throughout the life cycle of the device** with data obtained from the implementation of the manufacturer's post-market performance follow-up plan (referenced in Part B of Annex III, as part of the performance evaluation and the post-market surveillance system, referred to in Article 10(9)).
4. Specific requirements for the clinical performance studies to include
    a. the purpose of the study, which cannot be determined by analytical performance studies, literature or previous experience gained by routine testing
    b. Ethical principles to be applied to all aspects of the clinical study
5. Specific detailed requirements for methods used in clinical performance studies, including:
    a. Clinical performance study design type.
    b. Detailed requirements for the clinical performance study plan.
    c. Clinical performance study report.
6. Provision that where “other performance studies” are conducted, that the same requirements apply as those for clinical performance studies.