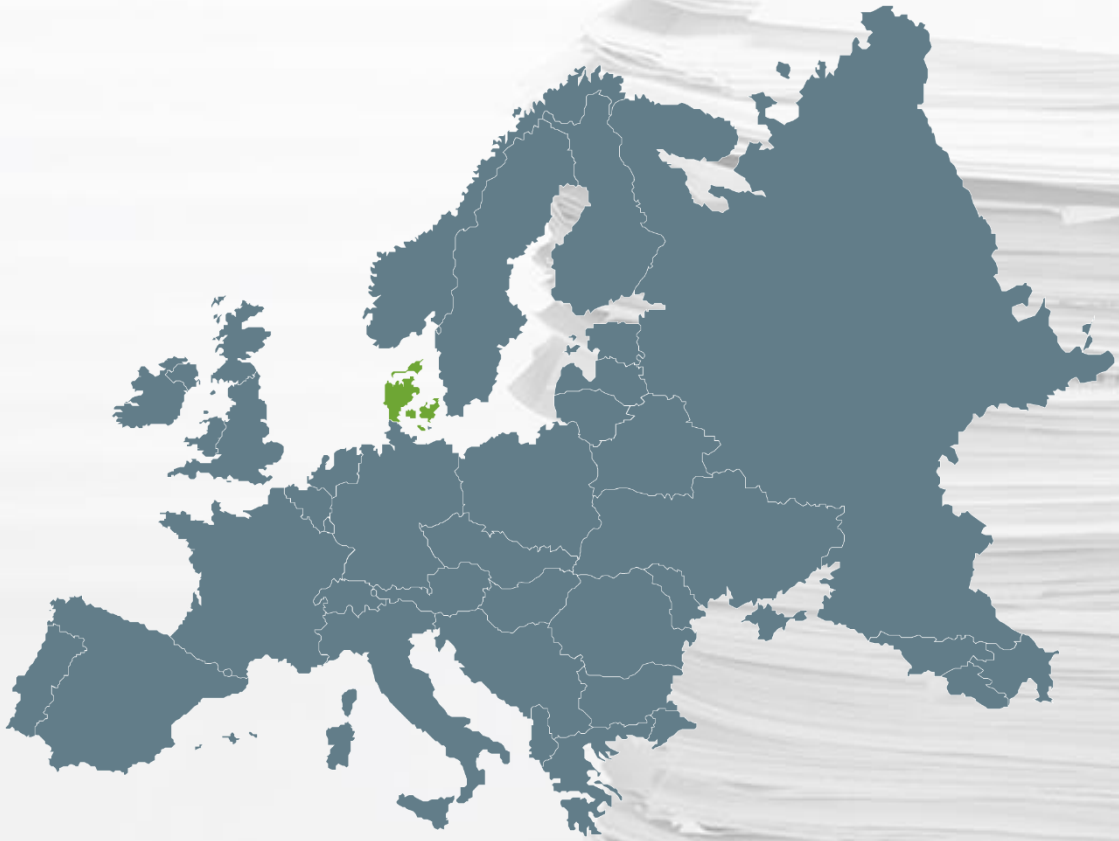
Annex IX

Conformity Assessment based on a Quality Management System and on assessment of Technical Documentation



How ready are you for the Medical Devices Regulation (MDR)?

The MDR (EU) 2017/745 which replaces the MDD (93/42/EEC) and AIMDD (90/385/EEC) has a transition period of three years. Manufacturers have the duration of the transition period to update their technical documentation and processes to meet the new requirements.

The scope of the new MDR (EU) 2017/745 is significantly increased compared to the MDD (93/42/EEC).

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The MDR (EU) 2017/745 which replaces the MDD (93/42/EEC) and AIMDD (90/385/EEC) has a transition period of three years. Manufacturers have the duration of the transition period to update their technical documentation and processes to meet the new requirements. The scope of the new MDR (EU) 2017/745 is significantly increased compared to the MDD (93/42/EEC).

The Regulation stipulates that the QMS should set high standards and support quality beyond simply satisfying compliance requirements for performance safety and outcomes.

This will require additional planning and training on changes across the entire quality system with the addition of new SOPs, manuals and reporting functions.

Advancing QMS to align with the new regulatory landscape is likely to require increased resources in order to maintain its ongoing management.

Notified Bodies are required to perform yearly assessments of QMSs and an unannounced inspection at least once every five years.

Manufacturers must ensure that internal auditors, quality teams, and regulatory personnel are properly versed and prepared to handle these delicate situations.

The MDR date of application coincides closely with the transition of the ISO13485:2016 standard.

Manufacturers should be aware that while implementation of ISO13485:2016 is a good QMS solution, a fully MDR compliant QMS will include further requirements which are not part of the ISO13485:2016 standard today.

All of these changes will need to be carefully planned, with gaps identified and action plans in place to ensure you are in a position to comply when the due date looms.

The correlation between ISO 13485:2016 and the new regulations will need to be well understood as simply complying with ISO 13485:2016 will not automatically infer compliance with either of the EU MDR and IVDR changes.

It is important to understand the regulation requirements and incorporate those into your QMS as you are transitioning to ISO 13485:2016.

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The Conformity Assessment route

To obtain CE marking certification, you must comply with European Commission Regulation (EU) 2017/745, commonly known as the Medical Device Regulation (MDR).

Appoint a Person Responsible for regulatory compliance

Determine classification of you device using Annex VIII (Classification Criteria) of the MDR

Class I	Class Is, Im or Ir	
Class IIb	Class IIa	Class III

Class I - Self-certified	Class Is, Im or Ir / Class IIa / Class IIb / Class III
Implement QMS. Notified Body intervention is not required	Implement a Quality management system (QMS) in accordance with the MDR. Most companies apply the EN ISO 13485 standard to achieve compliance. Your QMS must include Clinical Evaluation, Post Market Surveillance (PMS) and Post Market Clinical Follow-up (PMCF) plans. Make arrangements with suppliers about unannounced Notified Body audits.
Prepare CE **Technical File with CER according to Annex II and III**	In accordance with Annex II and III, prepare a **CE Technical File or Design Dossier** providing information about your device and its intended use plus testing reports, Clinical Evaluation Report (CER), risk management plan, IFU, labeling and more. Obtain a Unique Device Identifier (UDI) for your device
Appoint an **Authorized Representative** (EC REP) located in the EU who is qualified to handle regulatory issues. Place your EC REP name and address on device label. Obtain a Single Registration Number from **EUDAMED**	
No Notified Body audit of QMS or Technical File.	Your QMS and **Technical File or Design Dossier** must be audited by a Notified Body, a third party accredited by a European Competent Authority to audit quality management systems and products.
	You will be issued a CE Marking certificate for your device and an ISO 13485 certificate for your facility following successful completion of your Notified Body audit. ISO 13485, certification must be renewed every year. CE Marking certificates are valid for maximum of 5 years, but are typically reviewed during your annual surveillance audit.
Prepare a Declaration of Conformity in accordance with Annex IV - a legally binding document prepared by the manufacturer stating that the device is in compliance with applicable European requirements. You may now affix the CE Marking.	
Register the device and its Unique Device Identifier (UDI) in the EUDAMED database. UDI must be on label.	
Clinical evaluation and Technical File must be kept updated.	You will be audited by a Notified Body each year to ensure ongoing compliance with the MDR. Failure to pass the audit will invalidate your CE Marking certificate. You must perform Clinical Evaluation, PMS and PMCF activities to maintain certification.

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Quality management system assessment

You as manufacturer will need to establish, document and implement a quality management system as described in Art. 10(9) and maintain its effectiveness throughout the life cycle of the devices concerned.

As manufacturer you shall ensure the application of the quality management system as specified in MDR (EU) 2017/745 Annex IX.

Implementation of the quality management system shall ensure compliance with this Regulation.

All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programs, quality plans and quality records.

The manufacturer shall lodge an application for assessment of its quality management system with a Notified Body.

Not necessary for Class I products.

The application shall include:

- the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorized representative, the name of the authorized representative and the address of the authorized representative's registered place of business,
- all relevant information on the device or group of devices covered by the quality management system,
- a written declaration that no application has been lodged with any other Notified Body for the same device-related quality management system, or information about any previous application for the same device-related quality management system,
- a draft of an EU Declaration of Conformity in accordance with Art. 19 and Annex IV for the device model covered by the conformity assessment procedure,
- the documentation on the manufacturer's quality management system,
- a documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation and the undertaking by the manufacturer in question to apply those procedures,
- a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,
- the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Art. 87 to 92,
- a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Art. 87 to 92, as well as the undertaking by the manufacturer to apply those procedures,
- documentation on the clinical evaluation plan, and
- a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.

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Quality management system assessment and application with Notified Body access to technical documentation and this includes the following:

- New requirements vs MEDDEV 2.12.1 (Vigilance Reporting) i.e. maximum duration to report 15 days
- New requirements vs MEDDEV 2.12-2 (Post Market Clinical Follow-up) i.e. increased frequency of updates
- Process/Procedure for communication with Commission/Member States to obtain SRN
- Registration of Economic Operators including Single Registration Number (Art. 31)
- Systems for Market Surveillance (activities described in Art. 93)
- Systems for Serious Incident, Field Safety Corrective Action (Art. 87) and Trend Reports (Art. 88)
- Systems for PMS Plan and Report (Art. 84, Art. 85)
- Systems for Periodic Safety Update Report (Art. 86).

Additional QMS Requirements for MDR Applications. You will need to document information on:

- All systems for any reclassified devices or devices new to the scope of certification
- Economic Operators Registration (Art. 30) and Single Registration Number (SRN) (Art. 31)
- The new role of Person Responsible for Regulatory Compliance (Art. 15)
- Agreement with EU Authorized Representative i.e. written mandate (Art. 11), SRN (Art. 11), and including Person Responsible for Regulatory Compliance (Art. 15), QMS (Art. 8)
- Importers i.e. SRN (Art. 31), QMS (Art. 13)
- Distributors i.e. QMS (Art. 14)
- Strategy for Regulatory Compliance (Art. 10) Unique Device Identification and Registration (Art. 27, 29)
- Handling communication with regulatory authorities, Notified Bodies, Economic Operators
- Agreement with Importers / Distributors, including evidence of having met Art.13/14 respectively
- A process to identify Safety & Performance Requirements (SPR).

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MDR Conformity Assessment Procedure for CLASS I devices

Annex I	General Safety and Performance Requirements
Annex II	Technical Documentation
Annex III	Technical Documentation on Post Market Surveillance
Annex IV	EU Declaration of Conformity
Annex VI	UDI-Unique Device Identification
Annex VIII	Classification Rules

- MDR Conformity Assessment Procedure is similar to current MDD Annex VII EC Declaration of Conformity.
  - New EU Declaration of Conformity (new Art. 19) prepared by manufacturer,
  - Fulfill general obligation of all manufacturers (new Art. 10),
  - Involvement of a Notified Body is limited for Class I devices, and only required for
    - Is – sterile devices,
    - Ir – reusable surgical instruments or
    - Im – devices with a measuring function

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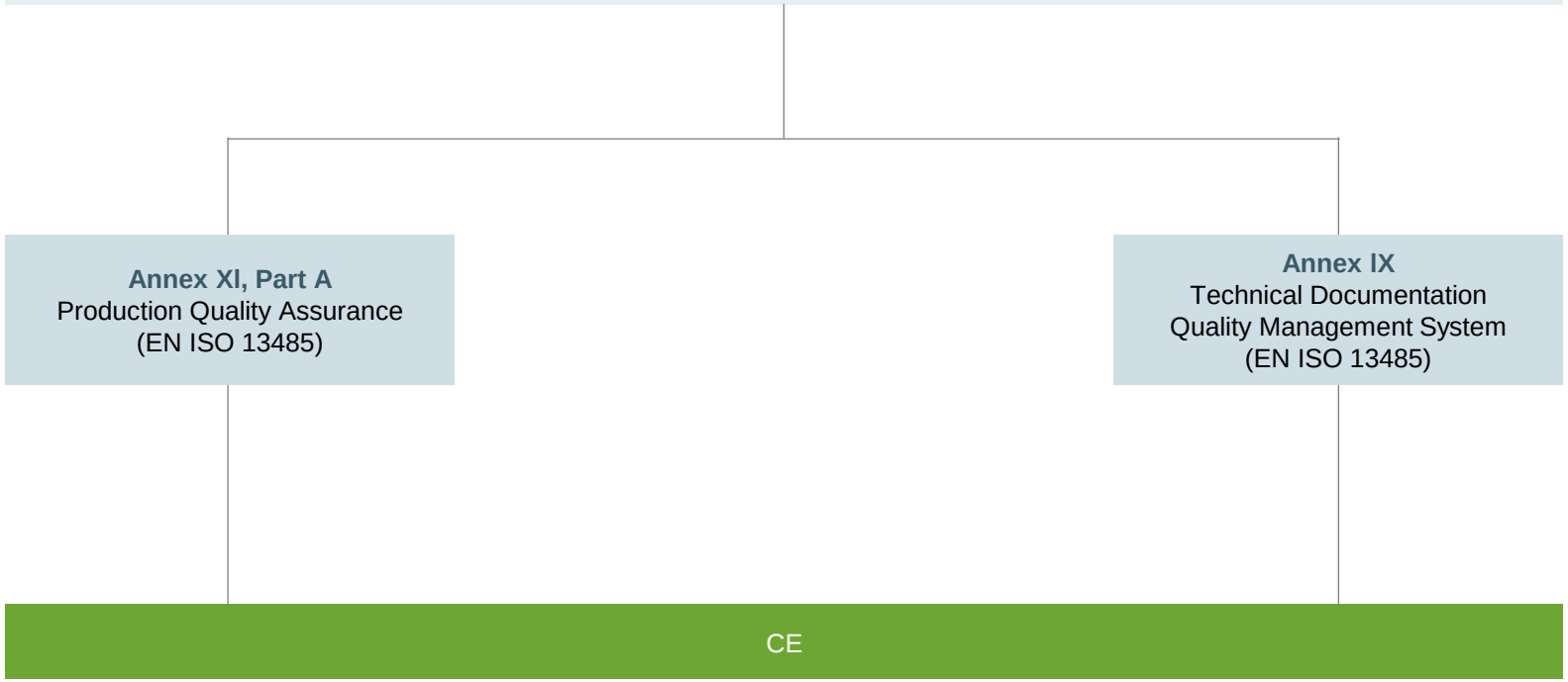
MDR Conformity Assessment Procedure for CLASS Is / Ir / Im devices

Annex I	General Safety and Performance Requirements
Annex II	Technical Documentation
Annex III	Technical Documentation on Post Market Surveillance
Annex IV	EU Declaration of Conformity
Annex VI	UDI-Unique Device Identification
Annex VIII	Classification Rules



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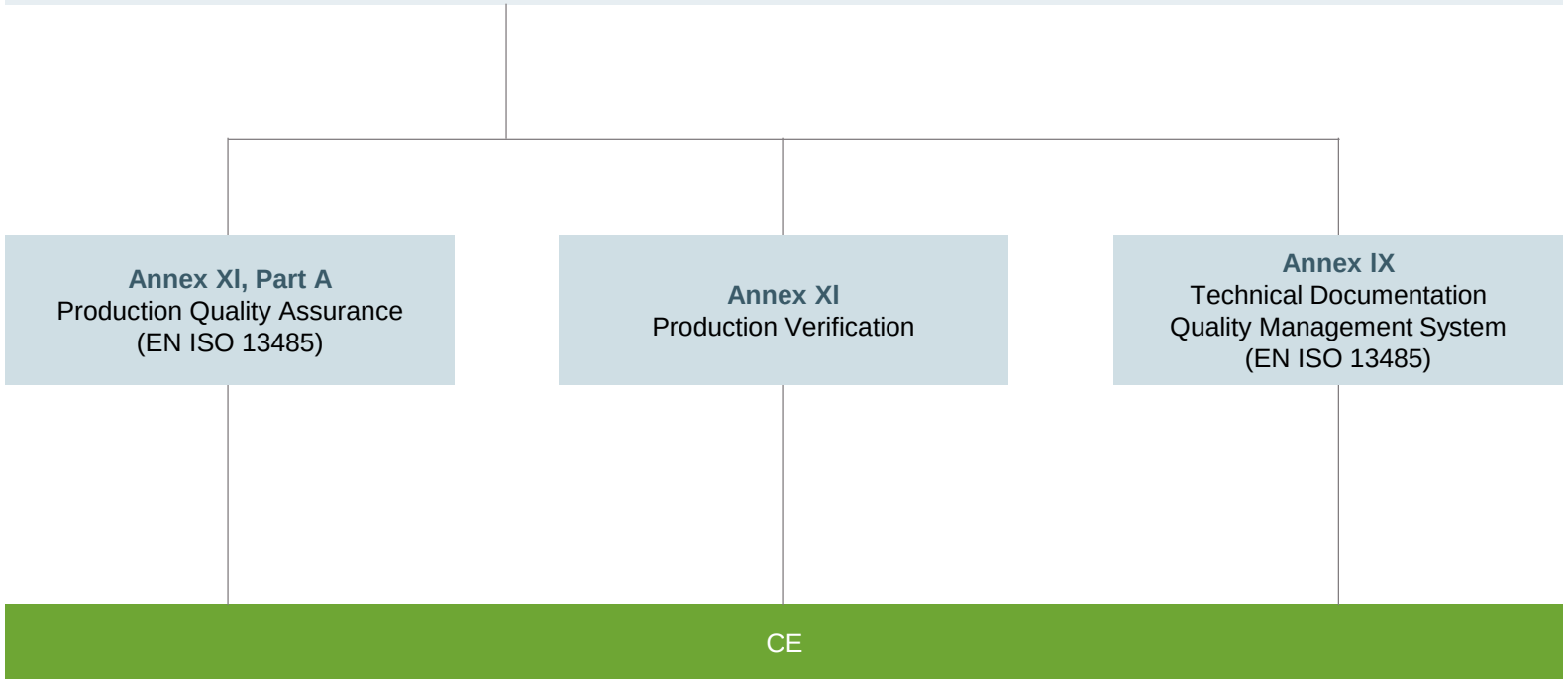
MDR Conformity Assessment Procedure for CLASS IIa devices

Annex I	General Safety and Performance Requirements
Annex II	Technical Documentation
Annex III	Technical Documentation on Post Market Surveillance
Annex IV	EU Declaration of Conformity
Annex VI	UDI-Unique Device Identification
Annex VIII	Classification Rules



- MDR Conformity Assessment Procedure is similar to current MDD, manufacturers of Class IIa devices have the option of following the same conformity assessment route as for Class IIb devices, the new EU MDR´s Annex IX, with the Notified Body only assessing representative technical documentation.
- Manufacturers may choose not to follow the full quality management system approach essentially similar to current MDD´s Annex VII EC Declaration of Conformity combined with either Annex IV or AnnexV:
  - Compile the new technical documentation (new Annex II)
  - Manufacturer prepares the New EU Declaration of Conformity (new Art. 19),
  - and then the Notified Body either:
    - (a) assesses the Technical Documentation of a representative sample of the devices (Annex XI, Part A, section 10),
    - or (b) carries out tests to confirm the conformity of the devices (Annex XI, Part B, section 18).

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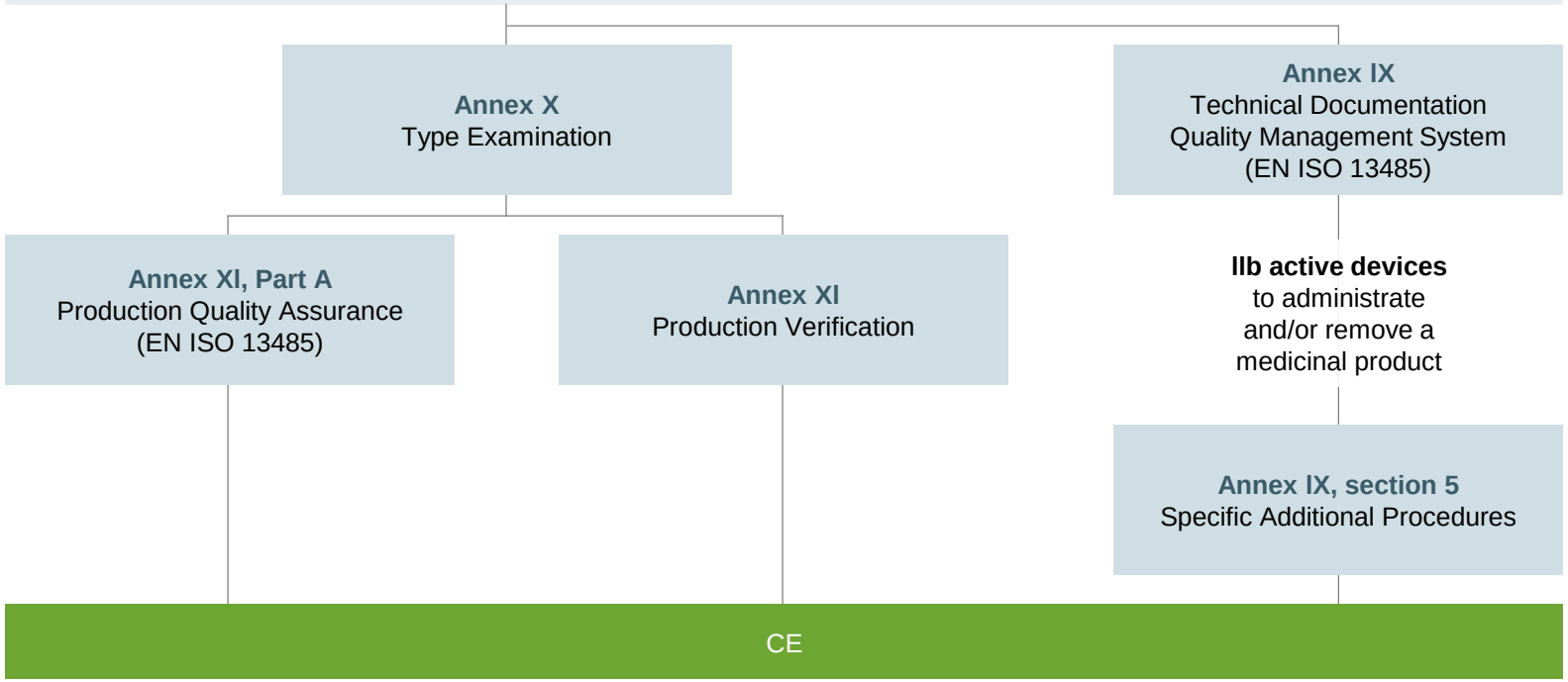
MDR Conformity Assessment Procedure for CLASS IIb devices

Annex I	General Safety and Performance Requirements
Annex II	Technical Documentation
Annex III	Technical Documentation on Post Market Surveillance
Annex IV	EU Declaration of Conformity
Annex VI	UDI-Unique Device Identification
Annex VIII	Classification Rules



- MDR Conformity Assessment Procedure is similar to current MDD, manufacturers of Class IIb devices have the option of following the same conformity assessment route as for Class III devices, the new EU MDR´s Annex IX, with the difference that the Notified Body is only required to assess the technical documentation of at least one representative device of each generic device group produced by the manufacturer.
- As with the current MDD, there are alternative routes for manufactures of Class IIb devices that chose not to follow the quality management system approach.
- These are the same as those for Class III devices with fewer alternatives available to manufacturers of Class IIb devices compared to MDD: there is no equivalent to MDD´s Annex VI Product Quality Assurance".
- Manufacturers currently following this route will have to choose an option from the new Annex XI. Either Part A, Production Quality Assurance, or Part B, Product Verification.

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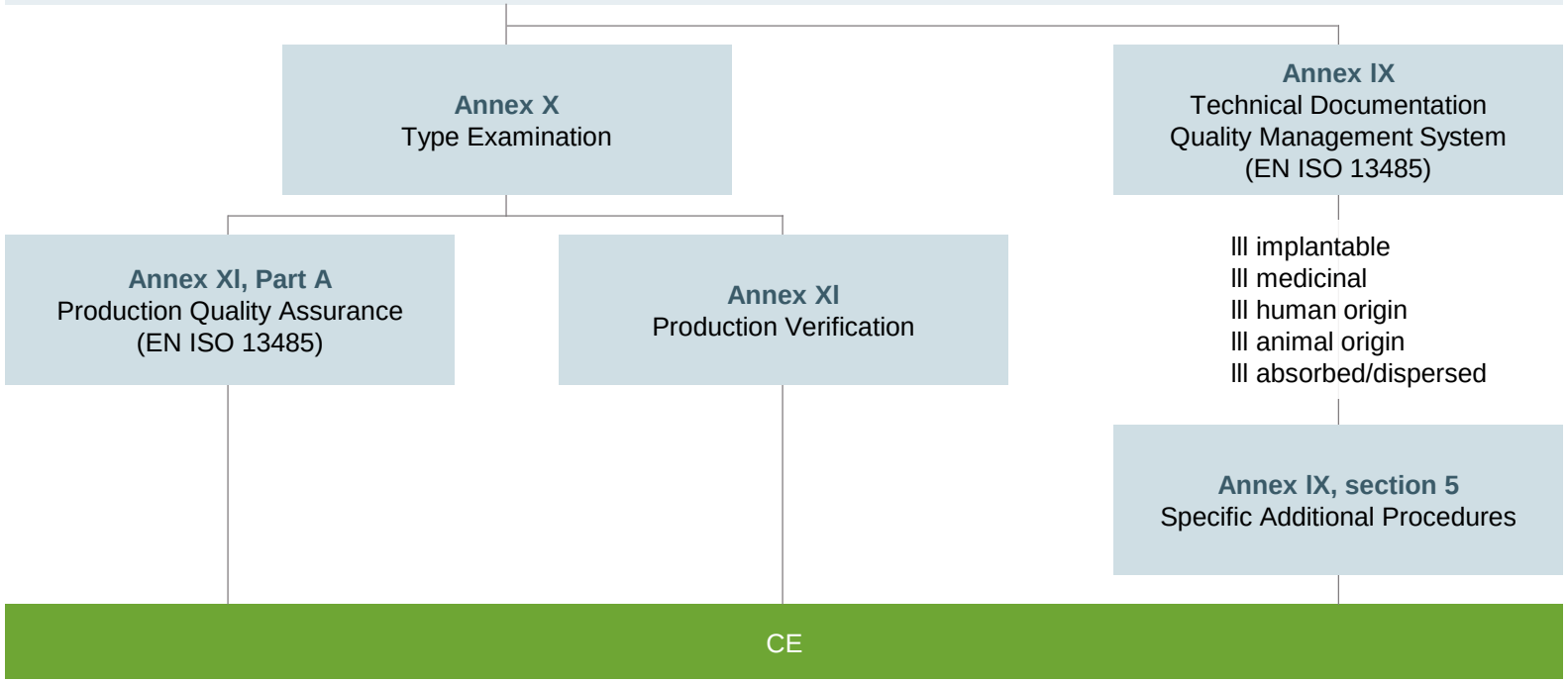
MDR Conformity Assessment Procedure for CLASS III devices

Annex I	General Safety and Performance Requirements
Annex II	Technical Documentation
Annex III	Technical Documentation on Post Market Surveillance
Annex IV	EU Declaration of Conformity
Annex VI	UDI-Unique Device Identification
Annex VIII	Classification Rules



- The current MDD´s Annex II Full Quality Assurance route will be replaced by the new MDR´s Annex IX Conformity Assessment based on Quality Management System Assurance and Assessment of the Technical Documentation.
- There are alternatives for those manufactures who chose not to follow the full quality management system approach: the current MDD alternative for Class III devices of Annex III EC type-examination, combined with either Annex IV EC Verification or Annex V Production Quality Assurance will be replaced by the new EU MDR´s Annex X Conformity Assessment based on Type examination combined with new Annex XI Conformity Assessment based on Product Conformity Verification.
- This is essentially identical to those of the current MDD. The new EU MDR´s Annex XI Conformity Assessment based on Product Conformity Verification includes both the MDD´s current options; Part A being the new Production Quality Assurance route, replacing the current MDD´s Annex V Production Quality Assurance. Part B being the new Product Verification route, replacing the current MDD´s Annex IV EC Verification.

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Our employees have more than +25 years of experience with the full lifecycle of RA/QA within the medical device area. We pride ourselves of being on the forefront of legislation and interpretation of what is the impact for manufacturers and economic operators.

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