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Class III Device Technical Documentation and STED Mapping

Practical 19 - Regulatory documentation practical

Aim

To map a Class III device technical dossier and legacy STED headings to current requirements.

Principle

EU device conformity is assessed under the applicable MDR or IVDR framework, device classification and intended purpose. CE marking is not an EMA medicine marketing authorisation.

Materials and Requirements

- Fictional product or study case and controlled document templates
- Current official requirements for the specified jurisdiction and product category
- Requirement-to-evidence and gap-assessment worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Define product category, intended use, jurisdiction, application type and the date of the regulatory check. Keep this as an offline training exercise with no filing, fees or real applicant information.
3. Classify the fictional product as a device or IVD and document the applicable classification rule and intended purpose.
4. Map general safety/performance requirements to risk management, verification/validation, clinical evaluation or performance evidence and technical documentation.
5. Identify the appropriate conformity-assessment route and notified-body involvement where required, plus declaration, labelling and registration obligations.
6. Prepare post-market surveillance, vigilance and clinical/performance follow-up plans and check current transition rules for the actual case.
7. Perform an independent consistency and completeness check. Record evidence, gaps, owners and the exact approval or permission still required.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Requirement / dossier element	Document / evidence	Gap / responsible role	Readiness decision
Administrative scope	Identify	Assess	Record
Scientific / quality evidence	Map	Assess	Record
Submission / lifecycle	Validate	Assess	Record

Worked Example

Fictional Class III implant has bench evidence but no justified clinical evaluation. A completed checklist cannot replace the missing clinical evidence or notified-body assessment.

Technical-documentation mapping

• Organise device description, design/manufacturing, safety/performance checklist, risk management, verification/validation, clinical evidence and post-market plans.
• Treat STED as a summary structure. Map it to the actual jurisdiction current technical-documentation requirements; for EU MDR include Annex II and III scope rather than assuming STED alone is legally sufficient.

Result and Interpretation

• Deliver a conformity-assessment map with requirement-to-evidence traceability.
• A complete training checklist is not an authorisation, licence or guarantee of acceptance.

Precautions

• Distinguish scientific content requirements from electronic-publishing rules.
• Recheck current forms, amendments, scope and local requirements at actual filing.
• Do not invent approval numbers, signatures, fees or deadlines.

Viva Questions and Answers

Why define the application type first?

It determines the legal route and required evidence.

Does a valid file format prove scientific adequacy?

Technical validation and substantive review are separate.

Why retain requirement versions?

Regulations and submission specifications can change.

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