

MODERATE UNCERTAINTY

Verification Checklist

Know When Your Research is Complete and Current

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Section 1: The 10-Item Completeness Checklist

Did You Find Everything?

That nagging feeling that you might have missed something is common among regulatory professionals. This checklist gives you a systematic way to verify completeness.

THE GOAL

Move from "I think I found everything" to "I checked everywhere relevant and documented what I found."

For Any Regulatory Question, Check These 10 Sources:

- 1. Primary regulation text (MDR/IVDR/2001/83/EC)
- 2. Relevant annexes to the regulation
- 3. EMA guidelines specific to your topic
- 4. EMA Q&A documents
- 5. MDCG guidance documents
- 6. European Commission notices and FAQs
- 7. Coordination Group (CMDh/CMDv) guidance
- 8. Notified Body opinions (NBOG documents)
- 9. Recent amendments or corrigenda
- 10. Transition provisions (if applicable)

NOT EVERYTHING APPLIES

Not all 10 sources will be relevant to every question. Check each and note "N/A - not relevant" rather than skipping silently.

Section 2: Document Currency Verification

Is Your Document Current?

EMA and MDCG documents are updated without fanfare. A document you used six months ago may have been superseded. Here is how to verify currency.

- 1 Step 1: Check the Document Date**
Look for "Date of first publication" and "Date of last revision" in the header or footer.
- 2 Step 2: Search for Superseding Documents**
On the EMA website, search for the document title. If a newer version exists, it usually appears first.
- 3 Step 3: Check the MDCG Document Library**
The MDCG library shows revision numbers. "Rev.1" has been superseded if "Rev.2" exists.
- 4 Step 4: Review Recent "What's New" Pages**
Both EMA and EC publish monthly updates. Check for your topic in recent months.

Currency Verification Quick Reference

DOCUMENT TYPE	WHERE TO CHECK FOR UPDATES
EMA Guidelines	EMA website > Regulatory > Human medicines > Scientific guidelines
EMA Q&A	EMA website > search by document number (e.g., EMA/37991/2019)
MDCG Guidance	EC website > MDCG documents > filter by topic
MDR/IVDR	EUR-Lex > search regulation number > check consolidated version

PRO TIP

EUR-Lex consolidated versions include all amendments. Always use the consolidated version, not the original OJ publication.

Section 3: Cross-Reference Quick-Reference

Which Documents Cite Which?

Regulatory documents form a web of cross-references. Understanding these connections helps you find related guidance.

Drug-Device Combination Cross-References

IF YOU'RE READING...	ALSO CHECK...
MDR Article 117	EMA DDC Guideline, MDCG 2022-5
EMA DDC Guideline	EMA DDC Q&A, MDR Annex I Chapter III
MDCG 2022-5 (Borderline)	EMA DDC Q&A Section 2
Directive 2001/83/EC	MDR Article 117(2) for device requirements

General MDR Cross-References

- Classification rules (Annex VIII) 'MDCG 2021-24 (classification guidance)
- Clinical evidence (Article 61) 'MDCG 2020-6 (clinical evaluation)
- UDI requirements (Article 27) 'MDCG 2019-1 (UDI guidance)
- Technical documentation (Annexes II & III) 'MDCG 2019-9 (summary of safety)

SEARCH STRATEGY

When a document references another, click through. The referenced document often contains the detail you actually need.

Section 4: Research Log Template

Build Your Audit Trail

A research log serves two purposes: it prevents you from re-searching the same question, and it provides an audit trail if your conclusions are ever questioned.

Research Log Entry Template

TEMPLATE

Research Log Entry

- Date: [YYYY-MM-DD]
- Question: [Specific regulatory question in one sentence]
- Sources Checked: [List with dates of documents]
- Key Finding: [What the regulation/guidance says]
- Conclusion: [Your interpretation and recommendation]
- Confidence Level: [High/Medium/Low + reason]
- Next Review: [When to re-check for updates]

Example Entry

RESEARCH LOG

Date: 2025-01-15

Question: When is MDR conformity assessment required for DDC?

Sources Checked:

- MDR Article 117 (consolidated 2024-06)
- EMA DDC Guideline Rev.1 (2021-10)
- EMA DDC Q&A Rev.6 (2024-04)

Key Finding: Article 117(1) requires CE marking when device is integral. Q&A Section 3.2 clarifies "integral" definition.

Conclusion: Pre-filled syringe with specific design = integral, requires Notified Body opinion.

Confidence: High - explicit guidance exists

Next Review: Q2 2025 (check for Q&A updates)

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