Chapter 13 Checklist: Pre-Marketing Compliance Audit

Subtract to Ship: MDR Certification, Chapter 13: Pre-Marketing*

Instructions

Audit every piece of customer-facing content your company has produced. Do this today, not next week. Your Notified Body will Google your company during the audit. Any claim on your website that exceeds your technical documentation is a nonconformity finding. This checklist takes 1-2 hours and prevents weeks of remediation.

Part 1: Website and Online Presence Audit

Open every page of your website. For each page, check:

Page / URL	Medical claims found?	Claim matches intended purpose?	Action needed?
Homepage	Yes No	Yes No N/A	
Product page	Yes No	Yes No N/A	
How it works	Yes No	Yes No N/A	
About / Team	Yes No	Yes No N/A	
Blog posts	Yes No	Yes No N/A	
Other: _	Yes No	Yes No N/A	

Social Media Audit

Platform	Medical claims found?	Action needed?
LinkedIn company page	Yes No	
LinkedIn personal posts (founders)	Yes No	
Twitter / X	Yes No	
Instagram	Yes No	
Other: _	Yes No	

Language Check (Pre-CE vs. Post-CE)

Pre-CE permitted language: "We are developing..." / "Our team is working on..." / "The device is designed to..." / "We are pursuing CE certification for..."

Post-CE permitted language: "The device monitors..." / "The device detects..." / "Clinical evidence demonstrates..."

- [ ] All online content uses appropriate tense for our CE status
- [ ] No present-tense medical claims exist before CE marking

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Part 2: Demo Device Protocol

Question	Answer
Have you ever shipped a functional device outside your company?	Yes No
If yes, were all units clearly labelled "NOT FOR CLINICAL USE"?	Yes No Unsure
Did any demo device carry a CE mark?	Yes No Unsure
Can you trace every demo unit (who received it, when, current status)?	Yes No

Demo Device Protocol (create if you do not have one)

Element	Defined?
Who can authorise demo device distribution	Yes No
What labels demo devices carry	Yes No
What recipients are told about device status	Yes No
How demo devices are tracked	Yes No
How demo devices are retrieved	Yes No

Part 3: Trade Fair Compliance (Article 21(3))

If you attend trade fairs with pre-CE devices:

- [ ] Visible sign displayed stating device does not conform with MDR
- [ ] Sign states device is for presentation/demonstration purposes only
- [ ] Sign states device cannot be made available until compliant
- [ ] No CE mark on any displayed device
- [ ] Staff trained to respond "not yet available" to purchase enquiries

Part 4: Investor Materials Audit

Material	Medical claims present?	Public or private?	Action needed?
Current pitch deck	Yes No	Public Private	
One-pagers / brochures	Yes No	Public Private	
Deal room documents	Yes No	Public Private	
Event presentations	Yes No	Public Private	

Private investor communications (closed meetings) may contain clinical information. Public materials (event platforms, websites, social media) must not make medical claims before CE marking.

- [ ] Two versions exist: one for private investor meetings, one for public use

Part 5: The Five Pre-Marketing Rules

Rule	Compliant?
Rule 1: Marketing claims are a SUBSET of technical documentation claims. Never more.	Yes No
Rule 2: Demo devices are labelled as demo devices. Always.	Yes No N/A
Rule 3: Trade fair presence follows Article 21(3) with visible sign.	Yes No N/A
Rule 4: Online presence uses developmental language until CE.	Yes No
Rule 5: Regulatory reviews all customer-facing content BEFORE publication.	Yes No

Part 6: Claim-to-Documentation Traceability

Take your most prominent marketing claim. Trace it:

Element	Reference
Marketing claim (exact wording)	
Intended purpose statement (DD-002) that supports it	Section:
Clinical evidence that proves it	Document ID:
Risk-benefit analysis that justifies it	Document ID:

If you cannot complete this trace: the claim is unsupported. Remove it or build the evidence.

Part 7: Process Implementation

- [ ] A person with regulatory knowledge reviews marketing content BEFORE publication
- [ ] This review process is documented (who reviews, how, when)
- [ ] Marketing team understands Article 7 (claims) and Article 2(27-28) (market placement)
- [ ] Marketing and regulatory have compared intended purpose vs. website copy word by word

Findings and Actions

Finding	Priority	Action	Owner	Due Date
	Critical Important			
	Critical Important			
	Critical Important			
	Critical Important			

Audit date:

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Audited by:

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Next review date:

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