Chapter 1 Worksheet: Is Your Product a Medical Device?

Subtract to Ship: MDR Certification, Chapter 1: Why MDR Doesn't Have to Kill Your Startup*

Instructions

This worksheet helps you determine whether your product falls under MDR scope before you commit resources to certification. Complete it honestly. Ambiguity here costs years downstream. Spend 60-90 minutes on this exercise with your founding team.

Part 1: Product Description

What does your product do? (Plain language, no marketing copy)

What technology does it use?

Who uses it? (Be specific: role, setting, context)

Part 2: The MDR Article 2(1) Test

MDR defines a medical device based on its **intended purpose**. Answer each question with Yes / No / Unclear.

Question	Yes / No / Unclear
Is your product intended to diagnose a disease or condition?	
Is your product intended to prevent a disease or condition?	
Is your product intended to monitor a disease or condition?	
Is your product intended to predict or prognose a disease or condition?	
Is your product intended to treat or alleviate a disease or condition?	
Is your product intended to investigate, replace, or modify anatomy or a physiological process?	
Is your product intended to control or support conception?	
Does your product fall under MDR Annex XVI (products without an intended medical purpose)?	

If you answered "Yes" to ANY of the above: Your product is likely a medical device under MDR.

If you answered "Unclear" to ANY of the above: You are in the most dangerous position. Ambiguity in intended purpose is the single most costly starting point. Get expert input before proceeding.

If you answered "No" to ALL of the above: Your product may not be a medical device. Document your reasoning and verify with an expert.

Part 3: The ICD Check

Does your intended purpose reference a condition listed in the WHO International Classification of Diseases (ICD)?

- [ ] Yes, almost certainly a medical device
- [ ] No, may not be a medical device (verify further)
- [ ] Unsure, research the specific condition

Condition referenced (if any):

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Part 4: The Beachhead Assessment

Can your product serve a legitimate **non-medical** function?

- [ ] Yes, consider launching as a wellness product first (Chapter 5 Beachhead Strategy)
- [ ] No, the product is inherently medical (e.g., surgical instrument, implant)
- [ ] Possibly, needs expert analysis of the boundary

If you could launch as wellness first, what would the intended purpose statement say?

Part 5: The Tremitas Error Scan

Review the eleven errors from the Tremitas case. Check any that apply to your current situation:

- [ ] We have not clearly decided if we are a medical device or wellness product
- [ ] We have not spoken to a Notified Body or regulatory expert
- [ ] We are assuming regulatory costs will be manageable without specific numbers
- [ ] We do not have anyone on the team with MDR experience
- [ ] We plan to "deal with regulation later"
- [ ] Our timeline does not include regulatory milestones
- [ ] We have not validated our market beyond assumptions

Each checked box is a risk that compounds over time. Address them before spending on development.

Decision

Based on this worksheet:

- [ ] **We are building a medical device.** Next step: Chapter 2 (Product-Market Fit for MedTech)
- [ ] **We may not need to be a medical device.** Next step: Get expert verification of our positioning (Chapter 5)
- [ ] **We are unsure.** Next step: Schedule a 2-hour consultation with a regulatory expert who has classified 50+ devices

Date completed:

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Completed by:

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