Chapter 2 Worksheet: MedTech Product-Market Fit

Subtract to Ship: MDR Certification, Chapter 2: Product-Market Fit for MedTech

Instructions

Complete this worksheet before you spend a single euro on regulatory work. If you cannot fill in every field with answers grounded in real conversations (not assumptions), you are not ready for regulation. Block 2-3 hours. Be brutally honest.

Part 1: The One-Sentence Test

Write one sentence describing your target user, their problem, and your solution. **Do not use the word "innovative."**

Now check:

- ☐ I named a specific user (not "healthcare professionals", a specific role in a specific setting)
- ☐ I described a measurable problem (not "better outcomes", a specific pain point)
- ☐ I described what my device does (not what it is)
- ☐ I did NOT use "innovative," "revolutionary," "cutting-edge," or "novel"

Part 2: The MedTech Value Proposition Canvas

Map three profiles simultaneously. In MedTech, your device must solve a real problem for ALL three.

Profile 1: The User (Doctor / Nurse / Technician)

Element	Your Answer
Who specifically? (Name, role, department, hospital type)	
Their top 3 daily frustrations related to your device's domain	1.
	2.
	3.
How much time per patient does the current process take?	
How does your device change that time?	
Source of this information (name of person you spoke to)	

Profile 2: The Buyer (Procurement / Administration)

Element	Your Answer
Who approves this purchase? (Role, title)	
What is their approval threshold (EUR)?	
What budget line does your device fall under?	
What is their buying cycle? (Quarterly? Annual?)	
Source of this information (name of person you spoke to)	

Profile 3: The Payer (Insurance / Patient)

Element	Your Answer
Who ultimately pays? (Insurance, hospital budget, patient?)	
Is reimbursement available for this type of device?	
What is the cost per QALY justification?	
Source of this information	

Part 3: The 10-20x Test

What is your device replacing? (Even "doing nothing" counts)

On which dimension is your device better? (Time saved, cost reduced, errors avoided, staff hours freed)

By how much? _____ x better

Multiplier	Assessment
1-3x better	Nobody will switch. The hassle is not worth it.
3-10x better	Some early adopters might try it. Not enough for sustained sales.
10-20x better	Buyers will switch even if procurement takes 6 months.
20x+ better	You have a compelling value proposition. Verify it is real.

Is this multiplier based on measured data or assumptions?

☐ Measured (describe source): _____

☐ Assumed, **this is your next research task**

Part 4: Letters of Intent

LOI #	Institution	Contact Name / Role	Status	Date
1			☐ Requested ☐ Received	
2			☐ Requested ☐ Received	
3			☐ Requested ☐ Received	

If you cannot get 3 LOIs, the problem may not be urgent enough, or you are talking to the wrong people.

Part 5: Pre-Regulation Checklist

Answer with data from actual conversations, not assumptions.

Question	Your Answer	Source
How much time does your device save per procedure?		
How many patients can a clinician process with it vs. without?		
What does a typical day look like on the ward where your device will be used?		
What budget line does it come from?		
Who has to approve the purchase?		

If any field says "TBD" or "estimated", you have not done enough conversations.

Part 6: Reality Check Scorecard

Criterion	Grounded in evidence?
My target user is a specific person in a specific setting	☐ Yes ☐ No
I can name 3 real people who confirmed this problem exists	☐ Yes ☐ No
My "times better" number is based on measurement, not assumption	☐ Yes ☐ No
I have at least 1 LOI from a potential buyer	☐ Yes ☐ No
I can describe the user's daily workflow in their language	☐ Yes ☐ No

5/5: You are ahead of 90% of MedTech startups. Proceed to Chapter 3.

3-4/5: Good foundation. Close the gaps before committing to regulatory work.

0-2/5: You are not ready for regulation. Go back to customer conversations.

Date completed: _____

Completed by: _____

This worksheet is part of the Subtract to Ship: MDR Certification playbook by Felix Lenhard and Tibor Zechmeister. It does not replace professional regulatory advice.