

Chapter 3 Template: The MedTech Napkin Test

Subtract to Ship: MDR Certification, Chapter 3: Business Model Analysis

Instructions

This is the one-page business model test for MedTech startups. Fill it out before you spend a single euro on regulatory work. If the math does not fit on a napkin, you are overcomplicating it. Use real numbers from Chapter 2 research, not projections.

The MedTech Unit Economics Triangle

1. Revenue Per Unit

Field	Amount
Price per unit (what the market will pay, not what you hope)	EUR _____
Source of this number (Chapter 2 research, not assumption)	_____

2. Cost to Deliver Per Unit

Cost Component	Amount
Manufacturing cost per unit	EUR _____
Amortised regulatory cost per unit (total regulatory cost / projected 5-year sales volume)	EUR _____
QMS and post-market allocation per unit	EUR _____
Logistics, packaging, labelling per unit	EUR _____
Total Cost to Deliver	EUR _____

3. Customer Acquisition Cost (CAC)

Cost Component	Amount
Sales team (allocated per customer)	EUR _____
Clinical demonstrations	EUR _____
Trade fairs and marketing	EUR _____
Procurement cycle support	EUR _____
Total CAC	EUR _____

The Triangle Test

Calculation	Amount
Revenue per unit	EUR _____
Minus: Cost to deliver	EUR _____
Minus: CAC	EUR _____
= Gross Margin Per Unit	EUR _____

If gross margin is negative: **STOP**. Your business model does not work at these prices and costs.

The Full Napkin

Line Item	Amount
Revenue per unit	EUR _____
Units in Year 1 post-CE (be honest, 10-30 for most Class IIa hospital devices)	_____
Gross revenue Year 1 (revenue x units)	EUR _____
Gross margin per unit (from triangle above)	EUR _____
Pre-CE investment (everything before CE marking)	EUR _____
Pre-CE investment x2 (Double-It Rule)	EUR _____
12-month post-CE reserve (monthly burn x 12)	EUR _____
Total capital requirement (doubled pre-CE + 12-month reserve)	EUR _____
Payback period (total capital / (margin x units per year))	_____ years

The MedTech Allocation Method

When funding arrives, allocate BEFORE spending:

Bucket	% of Total	Your Amount
Bucket 1, Development (engineering, prototyping, testing)	40-50%	EUR _____
Bucket 2, Regulatory (QMS, NB, clinical evidence, technical file)	25-30%	EUR _____
Bucket 3, Post-CE Reserve (12 months operating expenses, untouched until CE)	15-20%	EUR _____
Bucket 4, Buffer ("we did not see this coming" fund)	5-10%	EUR _____
Total	100%	EUR _____

The Revenue Timeline Reality Check

Push your revenue start date 18 months to the right from CE marking. Does the company survive?

Period	Expected Activity	Expected Revenue
Months 1-3 post-CE	Preparing to sell (packaging, marketing, distribution)	EUR 0
Months 4-6 post-CE	First pilot customers (free or discounted)	EUR _____
Months 7-12 post-CE	Sales building slowly (3-9 month procurement cycles)	EUR _____
Months 13-18 post-CE	Approaching sustainable cadence	EUR _____

Is there enough cash to survive 18 months of minimal revenue after CE marking?

☐ Yes

☐ No, **fix this before starting regulatory work**

The De-Risking Ladder (Investor Readiness)

Track these metrics from Day 1:

Rung	Milestone	Status	Date Achieved
1	Problem validated (real clinicians confirmed need)	☐ Done	
2	Market sized (who buys, how many, at what price)	☐ Done	
3	Team qualified (regulatory competence present)	☐ Done	
4	Regulatory strategy defined (classification + conformity assessment procedure)	☐ Done	
5	QMS operational	☐ Done	
6	Clinical pathway planned	☐ Done	
7	Notified Body engaged	☐ Done	
8	Milestones hit on timeline	☐ Done	

Decision Gate

- ☐ The gross margin per unit is positive
- ☐ The payback period is under 5 years
- ☐ The total capital requirement is funded (or fundable)
- ☐ The revenue timeline survives an 18-month delay
- ☐ The allocation buckets are defined

All checked: Proceed to Chapter 4.

Any unchecked: The business model needs work before regulatory spending begins.

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.