Chapter 4 Template: Decision-Making Unit (DMU) Diagnostic

Subtract to Ship: MDR Certification, Chapter 4: Decision-Making Unit

Instructions

Map every person involved in buying your device BEFORE you spend a euro on sales. Complete one DMU Map per target customer type (e.g., one for regional hospitals, one for university clinics). Fill from real conversations, not assumptions. Mark any assumption with [VERIFY].

Part 1: DMU Map

Target customer type: _____

Target institution (if specific): _____

Role	Name (if known)	What They Care About	Authority (approve / recommend / block)	What They Fear	How to Reach Them
Clinical user (doctor/ nurse)					
Department head					
Procurement officer					
Hospital admin / C-level					
Budget committee / board					
IT / data protection officer					
Biomedical engineering					
Infection control officer					
Insurance / reimbursement					

Did you identify at least 5 roles? If only 3, you missed the IT department, data protection, or biomedical engineering. Go back and look.

Part 2: The Approval Architecture

Question	Answer
What is the approval threshold below which a department head can approve alone?	EUR _____
Above that threshold, who must approve?	_____
Does the budget committee meet monthly or quarterly?	_____
What budget category would your device fall under?	_____
Is there a different approval path for leasing vs. purchasing?	_____

If you do not know these numbers: This is the single most important piece of information to get before quoting a price. Ask your procurement contact directly.

Part 3: The Katrin Manoeuvre Assessment

Can your price be restructured to stay below approval thresholds?

Your device price	EUR _____
Approval threshold	EUR _____
Above threshold?	☐ Yes ☐ No

If above threshold, can you restructure as:

- ☐ Two separate line items (device + service/software)
- ☐ Lease instead of purchase
- ☐ Pilot programme under a different budget category
- ☐ Phased delivery across budget periods

Part 4: Channel Decision Framework

Device complexity: ☐ High ☐ Medium ☐ Low

Price point per unit: EUR _____

Direct access to clinical users in home market? ☐ Yes ☐ No

Can you afford direct sales? (Min. EUR 120,000-180,000/year for 1 clinical specialist + 1 commercial person) [ ] Yes ☐ No

Target markets in first 12 months: _____

Decision Logic

Your Situation	Recommended Channel
High complexity + high price + can afford direct	Direct in home market. Evaluate distributors after 12 months.
Medium complexity + medium price	Direct in home market + 1 distributor in 1 test market. Compare after 6 months.
Low complexity + high volume	Distributor-first, but keep 1 direct channel for feedback and PMS data.
Cannot afford direct at all	Distributor with strict performance clauses and country-by-country contracts.

Your channel decision: _____

Distributor Margin Math

Calculation	Amount
Your device price to end customer	EUR _____
Distributor margin (35-50%)	EUR _____
Your revenue per unit through distributor	EUR _____
Your cost to deliver per unit (from Chapter 3)	EUR _____
Net margin through distributor	**EUR _____**

If net margin is negative through distributor: you cannot use distributors. That is arithmetic, not preference.

Part 5: Three Real Conversations

Before finalising anything, have three conversations with **procurement officers** (not users, not department heads).

Conversation	Institution	Contact	Date	Key Insight
1				
2				
3				

Questions to ask:

1. “How do you typically evaluate new devices in this category?”
2. “What is the approval process for a purchase at this price point?”

3. “Who else would need to be involved in this decision?”
4. “What would make you confident enough to pilot this device?”
5. “What has gone wrong with new device purchases in the past?”

Part 6: MDR Tripwire Check

Review your pre-CE sales activities against MDR Article 2(27) and (28):

- ☐ We have NOT given functional devices to hospitals as “free trials”
- ☐ We have NOT left demo devices at hospitals for clinical use
- ☐ We understand that “free of charge” counts as “placing on the market”
- ☐ All pre-CE demos comply with Article 21(3) trade fair provisions
- ☐ No device outside our company carries a CE mark

Any unchecked box is a potential regulatory violation. Address immediately.

Decision Gate

- ☐ DMU mapped with at least 5 roles for our primary target customer
- ☐ Approval thresholds identified
- ☐ Channel decision made with margin math validated
- ☐ At least 1 procurement officer conversation completed
- ☐ Pre-CE sales activities are MDR-compliant

All checked: Proceed to Part II, The Regulatory Path (Chapter 5).

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.