Chapter 18 Template: MDR Budget, Timeline & Resource Planner

Subtract to Ship: MDR Certification, Chapter 18: Budget, Timeline & Resource Planning*

Instructions

Fill in real numbers from real conversations (regulatory consultants, Notified Bodies, test labs). If your numbers come from "I googled it" or "a friend told me," they are not real. Apply the Double-It Rule to every estimate. This template takes 1-2 hours and may be the most referenced page in your regulatory planning.

Part 1: Cost Estimate by Device Class

Select your class and fill in estimates:

Class I (No Notified Body)

Cost Item	Low Estimate	High Estimate	Your Estimate
NB fees	EUR 0	EUR 0	EUR 0
QMS setup	EUR 6,000	EUR 10,000	EUR _
Clinical evidence (literature-based)	EUR 10,000	EUR 30,000	EUR _
Biocompatibility testing (if applicable)	EUR 0	EUR 15,000	EUR _
Electrical safety / EMC (if applicable)	EUR 0	EUR 20,000	EUR _
External consulting / RA support	EUR 5,000	EUR 15,000	EUR _
Subtotal	**EUR 21,000**	**EUR 90,000**	**EUR _**
Double-It Rule applied	**EUR 42,000**	**EUR 180,000**	**EUR _**

Class IIa (Notified Body Required)

Cost Item	Low Estimate	High Estimate	Your Estimate
NB fees (initial certification)	EUR 25,000	EUR 40,000	EUR _
QMS setup	EUR 6,000	EUR 15,000	EUR _
Clinical evidence (literature-based)	EUR 50,000	EUR 80,000	EUR _
Biocompatibility testing	EUR 10,000	EUR 15,000	EUR _
Electrical safety / EMC	EUR 20,000	EUR 30,000	EUR _
HR idle time (NB review period)	EUR 60,000	EUR 120,000	EUR _
External consulting / RA support	EUR 20,000	EUR 50,000	EUR _
Subtotal	**EUR 191,000**	**EUR 350,000**	**EUR _**
Double-It Rule applied	**EUR 382,000**	**EUR 700,000**	**EUR _**

Class IIb (with Clinical Investigation)

Cost Item	Low Estimate	High Estimate	Your Estimate
NB fees (initial certification)	EUR 40,000	EUR 70,000	EUR _
QMS setup	EUR 10,000	EUR 25,000	EUR _
Clinical investigation	EUR 150,000	EUR 500,000	EUR _
Biocompatibility testing	EUR 10,000	EUR 20,000	EUR _
Electrical safety / EMC	EUR 20,000	EUR 30,000	EUR _
HR idle time (NB review + clinical)	EUR 100,000	EUR 200,000	EUR _
External consulting / RA support	EUR 30,000	EUR 80,000	EUR _
Subtotal	**EUR 360,000**	**EUR 925,000**	**EUR _**
Double-It Rule applied	**EUR 720,000**	**EUR 1,850,000**	**EUR _**

Part 2: The Hidden #1 Cost, HR Idle Time

Field	Your Numbers
Team size during NB review period	_ people
Average fully loaded cost per person per month	EUR _
Expected NB review duration	_ months
Estimated idle percentage during review	_%
Total HR idle cost	**EUR _**

This number does not appear on any NB invoice. It is often the single largest cost.

Part 3: Timeline Estimate

Class IIa Typical Timeline

Phase	Duration	Your Estimate	Start Date	End Date
QMS build	3-6 months			
Technical documentation	4-8 months (overlapping)			
NB application and review	6-12 months			
Addressing NB findings	2-4 months			
Certificate issuance	1-2 months			
Total to CE marking	**12-24 months**			

Adjustments

Factor	Add to Timeline
Team lacks regulatory experience	+6 months
Documentation needs major rework after NB review	+4 months
NB has a backlog	+3-6 months
Clinical investigation required	+6-24 months
Ethics committee approval (if clinical investigation)	+2-4 months

Your adjusted total timeline:

months

Part 4: Total Capital Requirement

Component	Amount
Pre-CE investment (from Part 1, doubled)	EUR _
12-month post-CE reserve (monthly burn x 12)	EUR _
Total capital requirement	**EUR _**

Post-CE Reserve Calculation

Field	Amount
Monthly burn rate (salaries, rent, insurance, etc.)	EUR _
x 12 months	
12-month post-CE reserve	**EUR _**

If your funding does not cover pre-CE (doubled) + 12-month post-CE reserve: you do not have enough funding.

Part 5: The De-Risking Ladder

Sequence your spending. Each rung validates the previous one.

Rung	Activity	Cost	Timeline	Status
1	Intended purpose + classification (1 consultation)	EUR 2,000-5,000	2-4 weeks	☐
2	Regulatory strategy + gap analysis	EUR 5,000-15,000	4-8 weeks	☐
3	QMS setup + Phase 2 start	EUR 15,000-30,000	3-6 months	☐
4	Testing + clinical evidence	EUR 30,000-500,000+	6-18 months	☐
5	NB submission + certification	EUR 25,000-100,000+	6-12 months	☐

Spend EUR 7,000 on Rungs 1-2 before spending EUR 100,000+ on Rungs 3-5.

Part 6: Funding Strategy (Austrian Startups)

Source	Applied?	Amount Expected	Status
FFG (e.g., BASIS programme)	Yes No	EUR _	Applied Approved Not yet
AWS	Yes No	EUR _	Applied Approved Not yet
EU programmes	Yes No	EUR _	Applied Approved Not yet
Angel investors	Yes No	EUR _	Applied Approved Not yet
Institutional investors	Yes No	EUR _	Applied Approved Not yet

Rule: Build your financial plan as if you will NOT get any public funding. If it arrives, it is a buffer. If it does not, you are still alive.

Part 7: Reality Check

Question	Answer
Where did your numbers come from?	Expert conversations Googled it Assumed
Does your budget include HR idle time?	Yes No
Does your timeline include NB review cycle?	Yes No
Does your financial plan survive 2x cost overrun?	Yes No
Do you have a 12-month post-approval reserve?	Yes No

If 3+ answers are "No" or "Assumed": your plan is not aligned with regulatory reality.

Date completed:

–

Completed by:

–

Total capital requirement: EUR

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Estimated timeline to CE:

months