Chapter 20 Template: The MDR Survival Checklist, Your Next 90 Days

Subtract to Ship: MDR Certification, Chapter 20: The MDR Survival Checklist*

Instructions

This is the master execution checklist. It compresses the 52-week roadmap from Chapter 20 into your immediate next 90 days, the foundation phase that determines everything. Each item traces to a specific chapter. Complete them in order. For each item, apply the STS filter: "What happens if I skip this?" If the answer involves patient risk or regulatory non-compliance, it stays.

Weeks 1-2: Verify and Define

Goal: Confirm you are (or are not) a medical device. Lock your intended purpose.

#	Action	Chapter	Status	Date
1	Read MDR Article 2(1). Determine if product meets the definition.	Ch 1	☐	
2	Write intended purpose in one paragraph (regulatory language, not marketing).	Ch 5	☐	
3	Run the ICD Check against your intended purpose.	Ch 5	☐	
4	Evaluate whether Beachhead Strategy (wellness first) is viable.	Ch 5	☐	
5	Get expert review of your intended purpose.	Ch 5	☐	
6	If medical device: accept it. If not: document why rigorously.	Ch 1/5	☐	

Week 1-2 output: Finalised intended purpose statement.

Weeks 3-4: Classify and Map

Goal: Classification confirmed. Conformity assessment procedure identified. Full regulatory landscape mapped.

#	Action	Chapter	Status	Date
7	Walk through ALL 22 Annex VIII classification rules systematically.	Ch 6	☐	
8	Apply the implementing rule (highest class from any applicable rule).	Ch 6	☐	
9	Determine conformity assessment procedure per Article 52.	Ch 6	☐	
10	Identify grey zones. Flag for expert consultation.	Ch 6	☐	
11	Map full regulatory landscape (RED, AI Act, national laws, standards).	Ch 5	☐	
12	Create regulatory requirements map (one page).	Ch 5	☐	

Week 3-4 output: Device classification + conformity route + regulatory requirements map.

Weeks 5-6: Team and QMS Foundation

Goal: Competence gaps identified. QMS Day 1 documents created.

#	Action	Chapter	Status	Date
13	Map team against required roles (PRRC, Risk Manager, QM Rep, Clinical).	Ch 7	☐	
14	Identify gaps. Define closing strategy (train/hire/outsource).	Ch 7	☐	
15	Engage external PRRC if needed (Article 15(2) for small enterprises).	Ch 7	☐	
16	Evaluate and select regulatory partner (5 criteria scorecard).	Ch 19	☐	
17	Write Quality Policy (1 page, signed by CEO).	Ch 8	☐	
18	Establish Document Control Procedure.	Ch 8	☐	
19	Write Risk Management Plan.	Ch 8	☐	
20	Write Design and Development Procedure.	Ch 8	☐	
21	Write CAPA Procedure.	Ch 8	☐	

Week 5-6 output: Competence gap analysis + 5 core QMS documents (8-14 pages total).

Weeks 7-8: Technical Documentation Framework + Clinical Strategy

Goal: Technical file skeleton built. Clinical evidence pathway selected.

#	Action	Chapter	Status	Date
22	Create Annex II folder structure with document ID system.	Ch 9	☐	
23	Start GSPR checklist (Annex I, every requirement: applicable or N/A).	Ch 9	☐	
24	Begin risk management file (EN ISO 14971).	Ch 9	☐	
25	If software: draft EN 62304 software development plan.	Ch 12	☐	
26	Determine which of 4 clinical evidence sources applies.	Ch 10	☐	
27	Check if recognised standards exist for your technology (Article 61(10)).	Ch 10	☐	
28	Assess equivalence viability (3 dimensions).	Ch 10	☐	
29	Conduct preliminary literature search.	Ch 10	☐	
30	Define clinical evidence strategy in writing.	Ch 10	☐	

Week 7-8 output: Technical documentation skeleton + clinical evidence strategy.

Weeks 9-10: Notified Body + Business Model

Goal: NB candidates identified. Business model validated against regulatory costs.

#	Action	Chapter	Status	Date
31	If Class IIa+: filter NANDO database for NB candidates.	Ch 11	☐	
32	Build short list of 3-5 NBs using five-variable framework.	Ch 11	☐	
33	Make first contact calls with top 3 NB candidates.	Ch 11	☐	
34	Run the MedTech Napkin Test with real regulatory cost numbers.	Ch 3	☐	
35	Apply Double-It Rule to all cost estimates.	Ch 18	☐	
36	Calculate 12-month post-CE reserve.	Ch 18	☐	
37	Confirm total capital requirement is funded (or fundable).	Ch 18	☐	

Week 9-10 output: NB short list + validated budget plan.

Weeks 11-12: Pre-Marketing + Phase Assessment

Goal: Pre-marketing clean. Phase 1/Phase 2 boundary clear.

#	Action	Chapter	Status	Date
38	Audit all website content for medical claims.	Ch 13	☐	
39	Audit all social media for medical claims.	Ch 13	☐	
40	Establish demo device protocol (if distributing any devices).	Ch 13	☐	
41	Implement regulatory review of marketing content before publication.	Ch 13	☐	
42	Determine Phase 1 vs. Phase 2 status for your development.	Ch 12	☐	
43	If Phase 1: define transition criteria.	Ch 12	☐	
44	If Phase 2: run feature subtraction audit (3-5 essential features).	Ch 12	☐	
45	Send Letter of Intent to selected NB (if Class IIa+).	Ch 11	☐	

Week 11-12 output: Clean pre-marketing + clear phase status + NB Letter of Intent sent.

90-Day Summary

Milestone	Completed?
Intended purpose finalised and expert-reviewed	
Classification confirmed with documentation	
Conformity assessment procedure identified	
Regulatory requirements map created	
Team competence gaps identified with closing plans	
QMS Day 1 documents created (5 core documents)	
Technical documentation skeleton built (Annex II structure)	
Clinical evidence strategy defined in writing	
NB candidates identified and contacted (if applicable)	
Budget validated with Double-It Rule	
Pre-marketing audited and clean	
Phase 1/Phase 2 boundary clear	
Regulatory partner engaged (if needed)	

Count of completed milestones: ____ / 13

13/13: You have completed the foundation phase. The puzzle makes sense. Proceed to full documentation build and NB submission.

10-12/13: Strong foundation. Close remaining gaps within 2 weeks.

7-9/13: Partial foundation. Prioritise the missing items, each gap compounds downstream.

Below 7/13: You are not ready for the next phase. Complete this checklist before committing significant budget to documentation or NB engagement.

The STS Filter, For Every Action

Before adding any task to your plan, ask:

"What happens if I skip this?"

- [ ] **Patient risk?** It stays. Non-negotiable.

- [ ] **Regulatory non-compliance?** It stays.
- [ ] **Neither?** It can be sequenced, simplified, deferred, or subtracted.

90-day plan start date:

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90-day plan end date:

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Completed by:

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