

Chapter 12 Worksheet: Two-Phase Approach, Phase Assessment & Transition

Subtract to Ship: MDR Certification*, Chapter 12: The Two-Phase Approach

Instructions

Determine whether you are in Phase 1 (R&D, "Does this work?") or Phase 2 (Medical Device Development, "Can we certify this?"). Starting Phase 2 too early wastes years on premature documentation. Starting Phase 2 too late creates regulatory risk. This worksheet helps you draw the line.

Part 1: Which Phase Are You In?

Question	Answer	Phase Indicator
Has your core technology been validated with bench tests or simulated data?	Yes No	No = Phase 1
Has your prototype been used on or near a patient?	Yes No	Yes = potential Article 62 territory
Is your intended purpose locked (not shifting)?	Yes No	No = Phase 1
Do you have a written EN 62304 software development plan (if software)?	Yes No N/A	No = Phase 1 code
Has market demand been validated with real evidence (LOIs, conversations)?	Yes No	No = Phase 1
Is your Phase 2 budget secured?	Yes No	No = stay in Phase 1

Assessment: - **I am in Phase 1.** Stay here until Phase 1 is done. Do not let investor pressure push you into Phase 2 prematurely. - **I am in Phase 2.** Verify you completed Phase 1 properly. - **I am unclear.** This ambiguity is your highest-risk item. Clarify this week.

Part 2: Phase 1 Checklist, "Does This Work?"

Activity	Status	Notes
Prototype development (rapid, iterative)	☐ In progress ☐ Not started	
Feasibility testing (bench tests, simulated conditions)	☐ In progress ☐ Not started	
Customer feedback on concept (NOT clinical use)	☐ In progress ☐ Not started	
Retrospective data analysis (if software)	☐ In progress ☐ Not started	
Market validation (Chapter 2 PMF work)	☐ In progress ☐ Not started	
State of the art / competitive analysis	☐ In progress ☐ Not started	

Phase 1 Red Line Check

- ☐ No prototype has been tested on patients
- ☐ No prototype has been used in clinical settings without ethics approval
- ☐ No informal "let me try this on a volunteer" testing has occurred
- ☐ All testing has been in lab, on simulated data, or on bench models

If any box is unchecked: you may have crossed into Article 62 territory. Address immediately.

Phase 1 Record-Keeping (not MDR-compliant, but retained)

- ☐ Lab notebooks maintained
- ☐ Test results recorded
- ☐ Design decisions documented with rationale
- ☐ Customer feedback notes captured

Part 3: Phase 1 to Phase 2 Transition Criteria

All five must be met before entering Phase 2:

Criterion	Met?	Evidence
Technology feasibility confirmed	Yes No	
Market demand validated	Yes No	
Intended purpose locked	Yes No	
Phase 2 budget secured	Yes No	
Feature scope subtracted to essentials	Yes No	

If any criterion is "No": you are not ready for Phase 2.

Part 4: Feature Subtraction Audit

Before entering Phase 2, list every feature. For each, apply the subtraction test:

Feature	Serves intended purpose?	Affects risk profile?	User would pay for it specifically?	Can be added post-certification?	Keep / Cut / Defer
	Yes No	Yes No	Yes No	Yes No	
	Yes No	Yes No	Yes No	Yes No	
	Yes No	Yes No	Yes No	Yes No	
	Yes No	Yes No	Yes No	Yes No	
	Yes No	Yes No	Yes No	Yes No	

Target: 3-5 essential features for Phase 2. Every additional feature adds weeks of documentation, testing, and NB review.

Essential features for Phase 2:

Features deferred to post-certification:

Part 5: Phase 2 Checklist, "Can We Certify This?"

Activity	Status	Notes
QMS operational (Chapter 8)	☐ In progress	
EN 62304 software development plan written (if applicable)	☐ N/A	
Risk management plan and initial analysis (EN ISO 14971)	☐ In progress	
Design inputs documented formally	☐ In progress	
Design and development procedure followed	☐ In progress	
Technical documentation structure established (Annex II)	☐ In progress	
Verification protocols written before testing	☐ In progress	
All design changes going through formal change control	☐ In progress	

Part 6: What Carries Over (and What Does Not)

From Phase 1	Carries to Phase 2 as...
Technology knowledge	Design inputs, risk analysis inputs
Feasibility data	State-of-the-art analysis, clinical evidence inputs
Design rationale	Design history file content
User feedback	Usability engineering inputs (EN 62366-1)

From Phase 1	Does NOT carry over
Code (for software devices)	Phase 2 code starts clean within EN 62304 plan
Prototype hardware	Phase 2 hardware uses design-controlled materials
Informal test results	Phase 2 testing follows formal protocols

Current phase: Phase 1 Phase 2 Transitioning

Transition date (actual or planned):

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Completed by:

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