

Chapter 5 Worksheet: Intended Purpose & Regulatory Landscape Map

Subtract to Ship: MDR Certification, Chapter 5: Understanding the Landscape*

Instructions

This is the most important exercise in the book. Your intended purpose statement drives classification, conformity assessment procedure, clinical evidence strategy, budget, and timeline. Spend two weeks getting this paragraph right. Get expert input. Two weeks of careful work here saves two years of regulatory rework.

Part 1: Intended Purpose Statement

Draft your intended purpose in one paragraph. Not marketing copy. Not investor pitch. The regulatory statement of what your product is intended to do, for whom, and in what context.

Self-Review Checklist

Read your statement back slowly. Check each item:

- ☐ Does it reference a specific disease, symptom, or medical condition?
- ☐ Does it use any of these words: diagnose, treat, monitor, prevent, alleviate, predict, prognosis?
- ☐ Cross-reference with the ICD, does it mention a condition listed there?
- ☐ Is it unambiguous? Could a regulator read it only one way?
- ☐ Does it match what your website says?
- ☐ Does it match what your pitch deck says?
- ☐ Does it match what your team tells potential customers?

If these four versions differ, you have four intended purposes. At most one of them is right.

Part 2: The ICD Check

Condition referenced in your intended purpose:

Is this condition in the ICD? - Yes, you are almost certainly building a medical device under MDR Article 2(1) - No, you may not be. Investigate further. - My intended purpose does not reference any medical condition

Part 3: Beachhead Strategy Assessment

Question	Answer
Can your product serve a legitimate non-medical function?	Yes No
Could you launch as a wellness product without medical claims?	Yes No
Is there revenue potential in the wellness positioning?	Yes No
Can you maintain discipline, no medical claims anywhere?	Yes No

If all four are Yes: The Beachhead Strategy may apply. Launch as wellness, build revenue, expand to medical later.

If any is No: Proceed directly with MDR certification.

Beachhead wellness intended purpose (if applicable):

Part 4: Regulatory Requirements Map

List every regulation, directive, and standard that applies to YOUR specific product.

Regulation / Standard	Applies? (Yes / No / Possibly)	Reason	Action Required
MDR (EU) 2017/745			
Radio Equipment Directive 2014/53/EU		Wireless communication (BT, WiFi, cellular, NFC)?	
EU AI Act 2024/1689		AI/ML components?	
IVDR (EU) 2017/746		In vitro diagnostic?	
General Product Safety Regulation		Consumer-facing?	
National law, Austria (MPAG)		Target market?	
National law, Germany (MPDG)		Target market?	
EN ISO 13485		QMS requirement	
EN ISO 14971:2019		Risk management	
EN 62304		Software component?	
EN 62366-1		Usability engineering	
EN 60601-1 series		Electrically powered?	
EN ISO 10993 series		Body contact?	
Other: _____			

Time to create this map: 2-3 days for a competent person. This prevents regulatory surprises in month 14.

Part 5: External Validation

- ☐ I have shown my intended purpose to someone NOT on my team
- ☐ Their assessment: This is a medical device wellness product unclear
- ☐ If they hesitated, the intended purpose needs more work
- ☐ I have consulted (or plan to consult) someone who has classified 50+ devices

Expert consulted:

Their assessment:

Part 6: Three Principles Checklist

- ☐ **Principle 1, Determine before you commit.** I have verified whether I need to be on the MDR path before telling investors, hiring consultants, or budgeting for conformity assessment.
- ☐ **Principle 2, Map the full landscape.** I have identified regulations beyond MDR that may apply (wireless, AI, national laws, international expansion).
- ☐ **Principle 3, Consider the beachhead.** I have evaluated whether a wellness-first launch is a viable strategy for my product.

Decision

- ☐ **My product is a medical device.** Next step: Chapter 6 (Classification)
- ☐ **My product is NOT a medical device.** Document reasoning. Consider anti-intended-purpose strategy (Chapter 19).
- ☐ **My intended purpose is still ambiguous.** Fix it before proceeding to classification.

Date completed:

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Completed by:

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Expert reviewer: