

# Regulatory Architecture Map

A one-page template for mapping the regulatory architecture of a digital health product. Complete in a PDF editor or print and fill by hand.

## 1. Feature inventory

Feature name	SaMD? (Y/N)	Est. class	Module assignment

## 2. Regulatory architecture

Non-SaMD features — no regulatory obligations · list features:

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<p><b>SaMD Module 1</b></p> <p>Module name: _____</p> <p>Class: _____ · Approved Body required: Y / N</p> <p>Certification route: _____</p> <p>Data flows in / out: _____</p>	<p><b>SaMD Module 2</b></p> <p>Module name: _____</p> <p>Class: _____ · Approved Body required: Y / N</p> <p>Certification route: _____</p> <p>Data flows in / out: _____</p>
<p><b>SaMD Module 3</b></p> <p>Module name: _____</p> <p>Class: _____ · Approved Body required: Y / N</p> <p>Certification route: _____</p> <p>Data flows in / out: _____</p>	<p><b>Arrows / data flows</b></p> <p>Each arrow should identify the data type being passed (for example mood check-in scores, conversation transcripts, risk flags), the direction of flow, and whether the receiving module's technical file documents the dependency and addresses the risk implications of the interface.</p> <p>_____ → _____ (label: _____)</p> <p>_____ → _____ (label: _____)</p> <p>_____ → _____ (label: _____)</p>

## 3. Summary

Module	Class	Certification route	Approved Body required	Est. timeline	Est. cost range