# Bundling vs Separation — Quick Reference

A one-page reference card on when to separate digital health functions into distinct regulated products and when to bundle them.

| Five reasons to separate |
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| 1. The functions have materially different risk profiles. |
| 2. The functions have different intended users. |
| 3. The functions have different development cycles. |
| 4. The functions could be commercially separated. |
| 5. Bundling would drag a non-SaMD function into regulation unnecessarily. |

| Five reasons to bundle |
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| 1. The functions form a single clinical pathway with interface risk if separated. |
| 2. The functions share the same intended purpose and intended users. |
| 3. The functions are meaningless without each other. |
| 4. The functions are always updated together. |
| 5. Separation would create more regulatory complexity than it resolves. |

## The three patterns

| Pattern | Recommendation |
| --- | --- |
| Foundation + add-on | Separate. Regulate the SaMD module only; iterate the foundation freely. |
| Assessment + intervention | Bundle. One clinical pathway, one technical file. |
| Consumer + clinical | Separate entirely. Different products, different users, different regulatory status. |

**Key principle:** the classification of a bundled product is determined by its highest-risk function. Separation protects lower-risk functions from higher-risk obligations and allows independent iteration.