

Separation Decision Workbook

A structured worksheet for deciding how a digital health product should be regulated: as one bundled medical device, or as two or more separate products. Complete each section in order.

1. Product description

Product name

Version / build

Intended use summary

2. Feature inventory

Each entry should represent a functionally distinct component with its own intended purpose and user population. A single named feature such as “AI chatbot” may need to be listed as multiple rows if it contains components with different classification implications. When in doubt, list at a finer level of granularity and consolidate later.

Example only — fictional product (Kova: conversational AI companion for young people aged 16–25 on an NHS IAPT waiting list)

Feature	Intended user	Intended purpose	SaMD? (Y/N/?)	Est. class	Dev cycle	Sellable alone?
Conversational AI	Young person	Therapeutic support and mood management	Y	III	Frequent	Y
Weekly mood check-in trend chart	Young person	Self-monitoring	Borderline	I or IIa	Occasional	N
Parent / carer dashboard	Parent or carer	Monitoring and escalation support	Y	IIb	Occasional	Y

Blank inventory — complete for your product:

Feature	Intended user	Intended purpose	SaMD? (Y/N/?)	Est. class	Dev cycle	Sellable alone?

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Dev cycle: frequent / occasional / rare. Sellable alone: would the feature still make clinical sense if sold independently?

3. Separation questions

For each candidate split, answer the five questions. Separation is worth pursuing if you answer YES to two or more.

Candidate split (which features would be separated?)

Question	Y/N	Notes
1. Can the modules function independently?		
2. Are the risk profiles materially different?		
3. Are the intended purposes genuinely distinct?		
4. Do the development cycles differ significantly?		
5. Is separation commercially viable?		

4. Alternative regulatory architectures

Sketch two or three alternative architectures for this product. For each option, record the classification outcome and an estimated certification timeline.

Option A

Architecture sketch

Classification outcome · Estimated timeline

Option B

Architecture sketch

Classification outcome · Estimated timeline

Option C

Architecture sketch

Classification outcome · Estimated timeline

5. Recommendation

Recommended architecture

Primary reasons for this recommendation

Open questions to resolve before committing

Reviewer · Date
