Chapter 16 Template: Product Modification Assessment & Change Control

Subtract to Ship: MDR Certification, Chapter 16: Product Modifications*

Instructions

Every product change is a regulatory event. Use this template to assess whether a modification is significant (requires NB involvement) or non-significant (internal change control). Plan for modifications at the development stage, not during your first software update. Read MDCG 2020-3 Rev.1 before using this template.

Part 1: Change Request Form

Field	Details
Change request ID	CR-_
Date	
Requested by	
Description of proposed change	
Reason for change	Bug fix Feature addition Component substitution Manufacturing change Safety improvement Regulatory update Other: _
Affected documents	

Part 2: Significance Assessment (per MDCG 2020-3 Rev.1)

Device Changes

Question	Yes / No	If Yes: Likely Significant
Does the change affect the intended purpose?	Yes No	Significant, may trigger re-classification
Does the change affect device performance?	Yes No	Potentially significant
Does the change affect safety characteristics?	Yes No	Potentially significant
Does the change affect biocompatibility?	Yes No	Potentially significant
Does the change involve new materials?	Yes No	Potentially significant
Does the change involve a new manufacturing process?	Yes No	Potentially significant
Does the change affect the software's clinical function?	Yes No	Potentially significant
Does the change affect the risk classification of software?	Yes No	Potentially significant
Does the change affect cybersecurity?	Yes No	Assess significance

QMS Changes

Question	Yes / No	If Yes: Likely Significant
Does the change affect processes critical to device safety?	Yes No	Potentially significant
Does the change affect organisational structure for compliance?	Yes No	Assess significance
New PRRC?	Yes No	Potentially significant
Change in manufacturing location?	Yes No	Potentially significant
New sterilisation supplier?	Yes No	Potentially significant

Assessment Result

- [ ] **Non-significant change.** Implement through internal change control. Update technical documentation. No NB notification required.
- [ ] **Significant change.** Inform Notified Body BEFORE implementation (Annex IX Section 2.4 / Annex VII Section 4.9). Await NB review.
- [ ] **Borderline.** Consult with NB before implementing.

Part 3: Impact Assessment

Area	Impact?	Details	Documents to Update
Intended purpose	Yes No		
Risk management file	Yes No		
Clinical evaluation	Yes No		
GSPR compliance	Yes No		
Biocompatibility	Yes No		
Electrical safety	Yes No		
Software verification	Yes No		
Labels / IFU	Yes No		
PMS plan	Yes No		

Part 4: Accessory Scope Audit

Review every component bundled with your device:

Component	Must be part of certified system?	Can be bought off-the-shelf?	Action
	Yes No	Yes No	Keep in scope Remove from scope
	Yes No	Yes No	Keep in scope Remove from scope
	Yes No	Yes No	Keep in scope Remove from scope
	Yes No	Yes No	Keep in scope Remove from scope

Every component removed from scope = one less component that triggers modification procedures when changed.

Part 5: Supply Chain Risk Assessment

Critical Component	Current Supplier	Backup Supplier?	Backup Validated?
		Yes No	Yes No
		Yes No	Yes No
		Yes No	Yes No
		Yes No	Yes No

Every single-supplier component = a modification risk. Qualify alternatives during development, not during a crisis.

Part 6: Change Control Process Check

Element	Defined?
Who initiates a change request	Yes No
Who assesses significance (per MDCG 2020-3 Rev.1)	Yes No
Who approves implementation	Yes No
Who updates technical documentation	Yes No
Who notifies the NB (if significant)	Yes No
Timeline from request to implementation	Yes No

If any element is undefined: establish the process before your first post-CE modification.

Part 7: CAPA Integration

When PMS data or complaints trigger a modification:

Step	Completed?
Complaint/finding logged	
Root cause analysis performed	
Corrective action defined	
Preventive action defined	
Change request initiated (this form)	
Significance assessed	
Technical documentation updated	
Risk management file updated	
NB informed (if significant)	
Effectiveness verified	

Approval

Role	Name	Signature	Date
Change requester			
Significance assessor			
Approver			
QM representative			

Change request ID: CR-

Date completed:

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