

Design Control Phase Deliverables Matrix: Pediactric Blood Drawing Rev X[#1]	Date: 22/02/2023	DHF
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Student/Team	
Name	Responsibility
Hamida Giwa	Design Review1,
Fariha Fairoz	Project plan, Design Review 1
Tracy Lu	Design Review1
Fatimah Mumuney	Design Review1, User needs

PHASE 1 – USER NEEDS, PROJECT APPROVAL

ITEM #	Design Control Element	Responsibility	Completed	Element of DMR
1	Product Description	Fariha, Tracy, Fatima, Hamida	√	
2	Known user requirements	Tracy, Fatima, Fariha	√	
3	Market	Hamida	√	
4	Project Cost Estimate		<input type="checkbox"/>	
5	Regulatory path		<input type="checkbox"/>	
6	Phase 1 Design Review	Fariha, Tracy, Fatima, Hamida	√	
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PHASE 2 – DESIGN INPUT, SPECIFICATION AND PLAN

ITEM #	Design Control Element	Responsibility	Completed	Element of DMR
1	Product Design Specification	Fatima	<input type="checkbox"/>	√
2	Product Development Plan		<input type="checkbox"/>	√
3	User Needs	Fariha, Tracy, Hamida, Fatima	√	
4	Design Inputs	Fatima, Tracy, Fariha, Hamida	<input type="checkbox"/>	
5	Concept Sketches		<input type="checkbox"/>	
6	Phase 2 Design Review		<input type="checkbox"/>	
7			<input type="checkbox"/>	

PHASE 3 – DESIGN PROCESS, DESIGN OUTPUT

ITEM #	Design Control Element	Responsibility	Completed	Element of DMR
1	Documented Design Reviews		<input type="checkbox"/>	
2	Device Drawings		<input type="checkbox"/>	√
2	Specifications, Bill of Materials (X-revision)		<input type="checkbox"/>	√
3	Manufacturing and Inspection Procedures		<input type="checkbox"/>	√
4	Product Labeling		<input type="checkbox"/>	√
5	Product Packaging		<input type="checkbox"/>	√

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6	Technical File (if required)		<input type="checkbox"/>	
7	Regulatory Documentation		<input type="checkbox"/>	√
8	Design Verification, Testing		<input type="checkbox"/>	
9	Input/Output Verification		<input type="checkbox"/>	
10	Risk Management Plan		<input type="checkbox"/>	
11	Design FMEA		<input type="checkbox"/>	√
12	Material specifications		<input type="checkbox"/>	
13	Simulated Use		<input type="checkbox"/>	
14	Clinical Evaluation		<input type="checkbox"/>	
15	Inspection Records (First Article Acceptance)		<input type="checkbox"/>	
16	Validations Required (list)		<input type="checkbox"/>	
17	Process FMEA		<input type="checkbox"/>	√
18	Phase 3 Design Review			
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PHASE 4 – DESIGN TRANSFER

ITEM #	Design Control Element	Responsibility	Completed	Element of DMR
1	Risk Management Report			
2	Complete Design Transfer Form		<input type="checkbox"/>	
3	Specifications released at rev 0 w/change notice		<input type="checkbox"/>	√
4	Summary of change from rev X to rev 0		<input type="checkbox"/>	
5	Validations		<input type="checkbox"/>	√
6	Release and Distribution of Technical File (if required)		<input type="checkbox"/>	
7	Notification of Notified Body (if required)		<input type="checkbox"/>	
8	Phase 4 Design Review		<input type="checkbox"/>	
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