Healthcare Innovation Cycle – HealthTech Deliverables Matrix (EU)

Solution Name: _____ Date: _____

Milestone Name	Overall Description	Clinical	Market/Business	Regulatory/ Approvals	Technology
1) Need	Insights into unmet clinical needs and available solutions	☐ Unmet needs defined ☐ Disease state characterized	☐ Needs screening & selection ☐ Existing solutions characterized	NA	NA
2) Idea	Potential solutions to unmet need developed and evaluated	☐ Clinical workflow description ☐ Updated need description ☐ Feedback from >5 clinicians	☐ Competitive landscape ☐ Envisioned Value Proposition	☐ Medical device intended use ☐ Equivalent devices identified	☐ Paper Prototype ☐ Hypothesis & experimental design ☐ Idea screening & selection
3) Proof of Concept (PoC)	Key component concepts validated in models and value proposition articulated	☐ Feedback from clinicians in >5 settings ☐ Updated need description and workflow	☐ Competing solutions characterization ☐ Preliminary Value Proposition ☐ Path to Payment plan ☐ Stakeholder Map	☐ Preliminary classification ☐ Preliminary intended use ☐ Preliminary regulatory pathway	☐ PoC prototypes ☐ Demonstration results ☐ Institutional IP disclosure
4) Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	☐ Feedback from clinicians in >20 settings ☐ Updated need & workflow descriptions	☐ Feedback from >5 economic buyers ☐ Impact Plan (draft business plan) ☐ Advisory Board	☐ Draft Essential Requirements Checklist ☐ Draft Instructions for use ☐ Institutional approval request(s)	☐ “Works Like” & “Looks Like” prototypes ☐ Freedom to operate review ☐ Provisional IP filing ☐ Killer Experiment

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5) Proof of Value (PoV)	The potential of the solution to work and create value for all stakeholders is demonstrated (Initial commercial investment)	☐ Feedback from >100 clinicians and KOLs ☐ Animal/First-in-Man experiments ☐ Peer reviewed publication(s) ☐ Scientific Advisory Board	☐ Investor ready business plan ☐ Feedback from >20 economic buyers ☐ Key management team identified ☐ Initial seed investment	☐ Application form to national competent authority ☐ Data requirements ☐ Clinical Investigation approval(s)	☐ "Works Like/Looks Like" prototypes ☐ BOM, manufacturing plan, and costing ☐ Full IP application ☐ Killer technical experiment
6) Initial Clinical Trials (ICT)	Regulated production of prototypes and collection of clinical and economic data	☐ Conduct Phase 0 and/or 1 clinical trial(s) ☐ Peer reviewed publication(s)	☐ Economic data ☐ Feedback from >50 economic buyers ☐ 1st Institutional Investment	☐ Data requirements confirmation ☐ Pre-submission	☐ Manufacture GMP-compliant pilot lots.
7) Validation of Solution (VoS)	The solution is shown to be effective and its value to all stakeholders is validated	☐ Clinical efficacy trials ☐ Peer reviewed publication(s)	☐ Purchasing intent from >10 buyers ☐ 2nd round of institutional investment	☐ Complete Technical File ☐ Technical File submission to Notified Body (CE Mark)	☐ GMP Process Planning
8) Approval & Launch (A&L)	Institutional and regulatory approval received, and sales launched	☐ Training materials & support established ☐ Peer reviewed publication(s)	☐ Initial sales	☐ Registration and Listing (CE mark) ☐ CMS Coverage & CPT Code Determination	☐ Finalized GMP process

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9) Clinical Use (Use)	The solution is used successfully in day-day clinical practice	☐ Included in local practice guidelines ☐ Peer reviewed publication(s)	☐ Profitable sales	☐ Monitoring and Inspections	☐ Patents issued ☐ Improvement plan
10) Standard of Care (SoC)	The solution is recognized as the Standard of Care.	☐ Recommended practice by medical specialty	☐ Dominant market share	NA	NA