**PUF108: MEDICAL DEVICE INTRODUCTION FORM**

This document is used whenever additions, deletions, replacements or upgrades to existing devices where there is an impact to clinical practice, efficacy, process or patient care.

Any rational for change must be clearly identified including whether the request is for an addition, deletion or replacement product, and the change must be approved by the MD prior to commencing any process to change.

A medical devices is any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings.

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| **PART A – Approvals (To be completed by Procurement.)** | | | | |
| **Requested by:** |  | | | |
| **Position:** |  | | | |
| **Date of Request:** |  | | | |
| **Description of Medical Device:** |  | | | |
| **Justification:** |  | | | |
| * **Introduction of a new device** | | | |  |
| * **Replacement or alternative to an existing device** | | | |  |
| * **Upgrade of a device** | | | |  |
| * **Deletion of a device** | | | |  |
| **CAO - Budget Approval Prior to Research:** | | | | |
| **Estimated cost of introduction/replacement:** |  | | | |
| **Cost within Budget:** | **Yes** |  | **No** |  |
| **Cost approved:** | **Yes** |  | **No** |  |
| **CAO Approval:** | **Yes** |  | **No** |  |
| **MD-Approval Prior to Research:** | | | | |
| **MD Approval:** | **Yes** |  | **No** |  |
| **COO Approval Prior to Research:** | | | | |
| **COO Approval:** | **Yes** |  | **No** |  |
| **Completed by:** |  | | | |
| **Position:** |  | | | |
| **Date:** |  | | | |

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| **PART B – Procurement Consultation**  **(To be completed by Procurement)** | | | | | | | | |
| **Product Comparison (Description and Prices)** | | | | | | | | |
| **Option A** | **Description:** |  | | | | | | |
| **Price:** |  | | | | | | |
| **Option B** | **Description:** |  | | | | | | |
| **Price:** |  | | | | | | |
| **Option C** | **Description:** |  | | | | | | |
| **Price:** |  | | | | | | |
| **Availability and ongoing supply in the UAE:** | | | | | | | | |
| **Option A:** | | **Definite issue:** |  | **Potential Issue:** | |  | **No Issue:** |  |
| **Option B:** | | **Definite issue:** |  | **Potential Issue:** | |  | **No Issue:** |  |
| **Option C:** | | **Definite issue:** |  | **Potential Issue:** | |  | **No Issue:** |  |
| **Samples available:** | | **Yes** | | | **No** | | | |
| **Option A:** | |  | | |  | | | |
| **Option B:** | |  | | |  | | | |
| **Option C:** | |  | | |  | | | |
| **Completed by:** | |  | | | | | | |
| **Position:** | |  | | | | | | |
| **Date:** | |  | | | | | | |

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| **PART C- Literature Review (To be completed by the Clinical Services).** | | | | | |
| **Author ,Date, Country:** | **Patient Group:** | **Study Type (Level of Evidence):** | **Applies to option:** | **Outcome Key Results:** | **Study Weaknesses:** |
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| **Level of Evidence:**  Ia - Evidence from Meta-analysis / systematic reviews of Randomized Controlled Trials  Ib - Evidence from at least one Randomized Controlled Trial  IIa - Evidence from at least one well designed controlled trial which is not randomized  IIb - Evidence from at least one well designed experimental trial  III - Evidence from case, correlation, and comparative studies.  IV - Evidence from a panel of experts | | | | | |
| **Completed by:** | |  | | | |
| **Position:** | |  | | | |
| **Date:** | |  | | | |

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| **PART D.1 – Clinical Evaluation/ Clinical Equipment Test**  **(To be completed by the Clinical Services).** | | | |
| **Name of Tester:** |  | **Date of test:** |  |
| **Option A:** |  | | |
| **Option B:** |  | | |
| **Option C:** |  | | |

**Note: extra information to be printed and attached if needed.**

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| **PART D.2 – Clinical Evaluation/ Simulated Field Evaluation**  **(To be completed by the Clinical Services).** | | | |
| **Name of Tester:** |  | **Date of simulation:** |  |
| **Option A:** |  | | |
| **Option B:** |  | | |
| **Option C:** |  | | |

**Note: extra information to be printed and attached if needed.**

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| **PART E – Scoring Matrix**  **(To be completed by the Clinical Services and Procurement).** | | | | | | | | | | | | |
| **Scoring points:** | **1-Worst** | | | **2** | | **3- Middle** | | | **4** | | **5-Best** | |
| **Criteria:** | **Availability** | | **Cost** | **Suitability** | **Functionality** | | **Safety** | | **Evidence** | **Durability** | | **Total Score** |
| **Option A:** |  | |  |  |  | |  | |  |  | |  |
| **Option B:** |  | |  |  |  | |  | |  |  | |  |
| **Option C:** |  | |  |  |  | |  | |  |  | |  |
| **Recommended Option:** | | | | | | | | | | | | |
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| **Completed by:** | |  | | | | | |  | | | | |
| **Positions:** | |  | | | | | |  | | | | |
| **Date:** | |  | | | | | | | | | | |

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| **PART F – Conclusion (To be completed by Clinical Services)** | | | | | | | | | |
| **Description of Medical Device:** |  | | | | | | | | |
| **Progressed by:** | **Name:** |  | | | | | | | |
| **Signature/Date:** |  | | | | | | | |
| **Option Recommended:** | **Option A:** |  | **Option B:** | | |  | **Option C:** | |  |
| **Rationale:** |  | | | | | | | | |
| **Approved/ Not Approved:** | **MD:** |  | | | | | | | |
| **Signature/ Date:** |  | | | | | | | |
| **Approval from Purchasing Committee:** | **Yes** | | |  | **No** | | |  | |
| **Comments/ Remark:** | | | | | | | | | |
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