## Innovative Medical Device Summary Form

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| Innovative Medical Device Declaration Form | | |
| 1 | Applicant Name |  |
| 2 | Organization Information (name, address and contact information for company/university/manufacturer) |  |
| 3 | Device Name |  |
| 4 | Type of Medical Device (Medical Device (MD) or In-Vitro Medical Device (IVD) |  |
| 5 | Device History (If the device has been previously authorized, address previous history interaction with regulatory; such as, FDA, EU, TGA etc.) |  |
| 6 | Risk Class (A, B, C or D) and Rationale (Refer to Annex 5) |  |
| 7 | Choose the applicable Innovative Medical Device Designation Criteria | The medical device is designed with innovative  features in the technology, indications for use, or  performance attributes that have no equivalence in  the local/global market.  The medical device provides a considerable  clinical/medical advantage over existing alternative  treatments.  Other (explain in the below section) |
| 8 | Provide detailed rationale for considering the device as an Innovative Medical Device. |  |
| 9 | Intended Use  *Which may include:*   * Indication of the device (treat/prevent/diagnose/monitor) * Patient population (age/gender/disease) * Body parts affected   Intended user |  |
| 10 | Device Description  *Which may include:*   * Brief description (written/ diagram/picture)   Mechanism of action (how the device achieves its intended purpose) |  |
| 11 | Device Characteristics  (address all that apply)   * Software * Biologic * Single use * Sterile (sterilization method) * Material used (Animal origin/human/tissue/medicinal substance) * Duration of body contact   Other characteristics (reagents/components/accessories) |  |
| 12 | Level of Evidence  (identify and discuss)  Pre-clinical data:   * Animal studies * Usability study * Software validation * Sterilization validation * Risk-benefit analysis * Any other lab test   Clinical Investigation documentation and Investigator’s Brochure:   * Pilot Study (if applicable) * Pivotal Study (if applicable) * Primary safety endpoint identified: (if yes, describe) * Primary effectiveness endpoint identified: (if yes, describe)   Clinical Evaluation/Literature Review |  |
| 13 | Attestations: | I confirm that the information given in this form is true, complete and accurate. |
| 14 | Signature: |  |