## 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 innovativefeatures in the technology, indications for use, orperformance attributes that have no equivalence inthe local/global market. The medical device provides a considerableclinical/medical advantage over existing alternativetreatments. 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: |  |