**CHECKLIST FOR ENLISTMENT OR RENEWAL OF CLASS–A MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR LOCAL MANUFACURE.**

[Form-6 *rule 14(2)(a), 16(1), and 17(2)]*

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| **Sr.#** | **DESCRIPTION** | **SELECT (YES/NO/NA)** |
| **1.** | **Application on Form-6 (Duly signed & stamped)** |  |
|  | New Application |  |
|  | For Renewal purpose (copy of enlistment certificate & last renewal) |  |
|  | Provide the details of change of any particular of enlisted MD (in case of any proposed change). |  |
| **2.** | **Proof of fee deposited: (endorsed by Statistical officer.)** |  |
| **3.** | Attach copy of valid establishment license to manufacture MD. |  |
| **4.** | **Product Detail:** |  |
|  | Provided the Medical device brand & generic name. |  |
|  | Provided that the MD contain any active ingredient, poison or drug; |  |
|  | Provided the HS code/ GMDN code. |  |
|  | Provided the Shelf life & Storage condition: |  |
|  | Provided the Proposed MRP of medical device: |  |
|  | Provide the details of manufacturing & QC processes. |  |
|  | Provided the medical device only for export or to be placed in local market? |  |
|  | Provided the complete description, Key functional elements, formulation & composition with functionality: |  |
|  | Provided the Description of accessories, other MD and other products that are not MD intended to be used in combination; |  |
|  | Provided the List of various configurations to be registered; |  |
|  | Provided the Explanation of novel features, if any; |  |
|  | Provided the Indications (Diagnose, treat, prevent, cure/ mitigate); |  |
|  | Provided the Contraindications & Warnings to inform on specific risk or hazard to use medical device; |  |
|  | If **Active MD**, attach documentation on software validation studies to verify the correctness of software, shall include the results of all verification, validation and testing performed prior to final release. |  |
|  | Provided the Instructions for installation and maintenance. |  |
|  | Provided the Sample of labels and its packaging; |  |
|  | Provided the Promotional material and product brochures. |  |
| **5.** | Provided the Grouping of medical devices: |  |
|  | Provided List of constituent/components/ MD are grouped together. |  |
| **6.** | Provided the DECLARATION (on stamp paper) as per Form-6. |  |
| **7.** | Provided the readable softcopy along with application in USB/CD. |  |