|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Checklist for the initial submission of DI record into the GUDID** | | **Yes** | **No** | **N/A** |
| Is the Issuing Agency established as an acceptable supplier and recorded in the form F-002D Approved Supplier List (ASL)? |  |  |  |
| If applicable, is the 3rd Party Consultant established as an acceptable supplier and recorded in the form F-002D Approved Supplier List (ASL)? |  |  |  |
| If applicable, is the GMDN Agency established as an acceptable supplier and recorded in the form F-002D Approved Supplier List (ASL)? |  |  |  |
| Is the UDI on individual device labels and packaging configurations? |  |  |  |
| Form F-004B Device Identifier (DI) Record completed and approved by GUDID Regulatory Contact and Coordinator? |  |  |  |
| Is there a procedure in place to verify UDI prior to production? |  |  |  |
| Is the correct date format used? |  |  |  |
| Does the AIDC follow the issuing agency specifications? |  |  |  |
| Does the DHR include the UDI? |  |  |  |
| Is the labeling for a home-use device?  If yes, was the labeling submitted electronically to FDA? Date submitted: |  |  |  |
| Comments: | | | |
| **Checklist to determine if a new DI record needs to be submitted due to a change** | | | **Yes** | **No** |
| Does the change modify one of the following new DI trigger fields? | |  |  |
| * Issuing Agency | |  |  |
| * Primary DI Number | |  |  |
| * Device Count | |  |  |
| * Brand Name | |  |  |
| * Version or Model | |  |  |
| * Kit | |  |  |
| * Combination Product | |  |  |
| * For Single-Use | |  |  |
| * Device Packaged as Sterile | |  |  |
| * Requires Sterilization Prior to Use | |  |  |
| Existing DI Record Update Required  New DI Record required | | | |
| Comments: | | | |

|  |  |
| --- | --- |
| **LABELING CHECKLIST COMPLETED BY** | |
| Name (Print): | *Signature & Date:* |