**CHECKLIST FOR GRANT OR RENEWAL OF AN ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES.**

**[**Form-1 *rule 4(2), 5(1), and 6(2)]*

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| --- | --- | --- |
| **Sr.#.** | **DESCRIPTION** | **SELECT (YES/NO/NA)** |
| **1.** | **Application on Form-1 (Duly signed & stamped)** |  |
| 1.
 | New Application |  |
|  | For Renewal Purpose (copy of license and last renewal attached) |  |
|  | Provide the details of change of any particular of a licensed establishment (in case of any proposed change). |  |
| **2.** | **Proof of fee deposited: (endorsed by Statistical officer.)** |  |
| **3.** | **Establishment Details** |  |
| 1.
 | Provided the Establishment name, complete address, contact info. |  |
| 1.
 | Provided the Type of ownership i.e. partnership, proprietorship, public & private limited etc. (Documents of land required in all cases.) |  |
|  | In case of proprietorship: NTN, Online FBR Certification. |  |
|  | In case of public & private limited: SECP-Form-21, Form-29, NTN. |  |
|  | In case of partnership: NTN, Online FBR Certification, Partnership Deed, Certificate of Registrar of firms. |  |
|  | Provided the Names, photographs and copies of CNIC, of partners/proprietors/directors: |  |
|  | Provided premises details, triplicate copies of LOP with dimension: |  |
|  | Provided the Details of section wise equipment for manufacturing and instruments for quality control: |  |
| **4.** | **Detail of Qualified/ Technical Person**  |  |
|  | Provided the Name, photographs, Qualification, copies of CNIC, Degrees, experience certificate(s) and appointment letter of production in-charge for supervising manufacturing/ production department. |  |
|  | Provided the Name, photographs, Qualification, copies of CNIC, Degrees, registration certificate from concerned council (where applicable) experience certificates and appointment letter of QC in-charge for supervising QC department. |  |
|  | Provided the list of other technical staff working in these departments: |  |
| **5.** | Provided Details of medical devices intended to be manufactured: |  |
| **6.** | Provided the DECLARATION on stamp paper as per Form-1. |  |
| **7.** | Provide readable softcopy along with application in USB/CD. |  |