

[[1]](#footnote-1)**[DRUG REGULATORY AUTHORITY OF PAKISTAN**

**FORM-1(B)**

*[See rule 67(2)]*

**APPLICATION FORM FOR GRANT OR RENEWAL OF PERMISSION CERTIFICATE TO OUTSOURCE ANALYSIS OF MEDICAL DEVICES**

I/We ……………………………………………………………..………… (1) …………………………………….. (2) ……………………….… (attach list of partners/directors) holder(s) of CNIC Nos ….………………………….……… Owner/ Managing Director/ CEO) of M/s ………………………………………, having valid ELM…………………….. or applied on Form-1 vide DRAP diary No .………….… dated ……………...…….... hereby apply for certificate to outsource analysis of medical device(s) to …………………… (name of contract acceptor) for the following activities (1) ……………. (2) ……………..

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sr.** | **Description** | | | **Particular** | |
|  | **Purpose of application, whether;** | | | **Please select appropriate column** | |
|  | Fresh/New Application | | |  | |
|  | For renewal of permission certificate to outsource manufacturing processes of medical devices | | |  | |
| 1. Certificate number and date of issue: | | |  | |
| 1. Validity date: | | |  | |
| 1. Last renewal date and its validity: | | |  | |
| 1. Attach copy of certificate and last renewal: | | |  | |
| (iii) | Proposed change in any particular of the certificate (in case of any proposed change, please mention details of change) | | |  | |
|  | **Proof of fee deposited:** | | |  | |
|  | **Contract** between contract giver and contract acceptor (provide on stamp paper duly signed by both) | | |  | |
|  | **Contract giver details** | | | **Please provide detail against each where applicable** | |
|  | Establishment name, address, contact information; (Attach copy of ELM or DRAP Diary No. of Form-1 application) | | |  | |
|  | Details of medical device(s) for which outsourcing is intended to be performed | | |  | |
|  | Details of analysis processes of each device(s) for which outsourcing is intended to be performed | | |  | |
|  | **Contract acceptor details** | | |  | |
|  | Establishment name, address, contact information | | |  | |
|  | Type of ownership i.e proprietorship, partnership, public or private limited  (In case of proprietorship, provide: NTN, Online FBR certification  In case of partnership, provide: NTN, online FBR certification, Partnership deed, Certificate of registrar of firms  In case of public & private limited, provide: NTN, SECP Form 21, Form-29) | | |  | |
|  | Names of proprietor/partners/directors; (Also attach readable copies of CNIC) | | |  | |
|  | Residential addresses of partners/proprietors/directors | | |  | |
|  | Details of procedure for performing the outsourcing step(s), | | |  | |
|  | Details of all the tests to be performed including acceptance limit/criteria | | |  | |
|  | Materials to be used | | |  | |
|  | Standards applied (attach copies of standards) | | |  | |
|  | Analysis/testing protocols to be used (software validation protocol in case of active medical device testing), | | |  | |
|  | Copy of quality certificates such as ISO13485 etc (if any) | | |  | |
|  | Details of equipment/facility for performing the tests; | | |  | |
| Sr.No. | Name of Equipment | Make | Model | | Capacity |
| (1) | (2) | (3) | (4) | | (5) |
|  |  |  |  | |  |
|  |  |  |  | |  |
| (xii) | Sample report/certificate that will be provided to contract giver upon completion of analysis | | | | |
| (xiii) | Expertise available, their qualification and experience (provide names, CNIC(s), degree/certificate, experience letter(s) etc) | | | | |
|  | Any other relevant information that may be required by the MDB. | | |  | |

**DECLARATION**

Certified that the documents and information provided herein to outsource the activity as mentioned in the Form are genuine and correct; and if found at any stage to be misrepresenting or incorrect it shall lead to legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

This certificate must be on stamp paper to be provided by contract giver and contract acceptor duly notarized and signed and stamped by Proprietor/ Partner/Chief Executive/Managing Director

Name(s)………………..

Designations…………..

Signature(s)……………..

Stamp…………………..

Date…………………….

**Note:**

* This form shall also be used if change is proposed regarding the particulars provided in relation to the permission certificate to outsource manufacturing processes of medical devices. For this purpose, provision of relative information is mandatory.
* Provide readable softcopy along with application in USB/CD.”;

1. Inserted vide S.R.O. 559(I)/2022 dated 27th April, 2022. [↑](#footnote-ref-1)