To be published in the extra ordinary Gazette of Pakistan, Part-II

GOVERNMENT OF PAKISTAN
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
*****

Islamabad, the 27th April, 2022.

NOTIFICATION

S.R.O. 559(I)/2022.— In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, with approval of the Federal Government, is pleased to direct that the following further amendments shall be made in the Medical Devices Rules, 2017, namely,—

In the aforesaid Rules,—

(1) in rule 2, in sub-rule (1),—

(a) in clause (xlv), after the expression "sterilization", the expression "refurbishment" shall be inserted;

(b) after clause (lix), the following two new clauses (lix-a) and (lix-b) shall be inserted, namely.—

"(lix-a) "refurbished medical device" means a medical device the whole or any part of which has been substantially rebuilt, reequipped or restored, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and without prejudice to the generality of the foregoing, a refurbishment of a medical device may involve any or all of the following actions, namely:—

(a) stripping a medical device into component parts or sub-assemblies;
(b) checking parts of the medical device for suitability for reuse;
(c) replacing component part or sub-assemblies of the medical device that are not suitable for reuse;
(d) assembly reclaim or replacement component parts of the medical device or another medical device;
(e) testing the assembled medical device against the specifications of the original medical device or, if the product owner of the original medical device has revised those specifications, the revised specifications; or
(f) identifying the reassembled medical device as a refurbished medical device.;

(lix-b) "refurbishment" means a systematic process that ensures safety and effectiveness of the medical device without significantly changing the device's performance, safety specifications or changing the purpose originally intended by the product owner of the original medical device;";

(2) in rule 23, the existing rule shall be numbered as sub-rule (1) of rule 23 and thereafter, the following new sub-rule (2) shall be inserted, namely,—

"(2) If the MDB, on the basis of information received or on an inquiry conducted by it, is of the opinion that,—
(a) the import permit was procured by fraud or misrepresentation; or
(b) the circumstances in which an import permit was issued no longer exists; or
(c) it is necessary in the public interest to do so;
the MDB may, after affording to the import permit holder an opportunity of showing cause against the action proposed to be taken, cancel or suspend the import permit or specify any further conditions to which the permission shall be subject to and inform accordingly.";

(3) after rule 24, the following new rule shall be inserted, namely,—

"**24A. Import of medical devices for donation.**— Medical devices, including those the import of which is otherwise prohibited without enlistment or registration under the Drug Regulatory Authority of Pakistan Act, 2012 and these rules, may be imported for the purpose of donation, except products included in Schedule D and classes C and D, subject to the following conditions, namely:—
(a) the medical device shall not be sold or distributed in the market;
(b) documentary evidence or confirmation from website for free sale in the country of origin provided that in case of non-availability of such evidence, the importer shall be responsible for safety and performance of medical devices.
(c) the medical device shall not be used for the purpose of clinical trial, examination, test or analysis;
(d) clearance certificate must be obtained from the Assistant Director of the relevant field office or officer authorized of the Authority at the time of arrival of shipment. Consumption of utilization record must be obtained by the importer under the supervision of qualified technical staff as specified in these rules; and
(e) the medical device, where applicable, shall be preferably has six months of expiry or fifty percent of shelf life, whichever is less:

Provided that medical devices included in Schedule D and classes C and D may be imported for donation with the approval of the MDB or an officer authorized by it in this behalf.";

(4) rule 25 shall be omitted;

(5) for rule 27, the following shall be substituted, namely,—

"**27. No objection certificate for export.**— No objection certificate for export shall be issued to;

(i) the registered medical devices manufactured by the licensed manufacturers under the rule; or

(ii) the medical devices applied for registration by the licensed manufacturer under the rules.";

(6) rule 28 shall be omitted;

(7) after rule 34, the following new rule shall be inserted, namely,—

"**34A. Export of medical devices for donation.**— Medical devices, manufactured by licensed manufacturers, including those the export of which is otherwise prohibited without enlistment or registration under the Drug Regulatory Authority of Pakistan Act, 2012 and these rules, may be exported for the purpose of donation subject to issuance of NOC by the Assistant Director of relevant field office as per procedure and conditions determined by the MDB.";

(8) in rule 47,—

(a) in sub-rule (2), for the words "a sole representative", the words "representatives" shall be substituted; and

(b) in sub-rule (3), for the words "a sole representative", the words "its representative" shall be substituted;

(9) in rule 48, in sub-rule (1), the word "sole" shall be omitted;

(10) in rule 51, in sub-rule (1), for the proviso, the following shall be substituted, namely,—

"Provided that till establishment of a laboratory of the Authority, the Authority may, for the purpose of test and analysis, notify any other laboratory of repute and specify scope thereof.";

(11) in rule 67, for sub-rule (2), the following shall be substituted, namely.—

"(2) Outsourcing of manufacturing processes or analysis of medical devices may be allowed subject to the conditions laid down in Schedule F and for this purpose:—

(a) the licensed manufacturers of medical devices or the applicant of establishment license for manufacturing of medical devices shall apply to the MDB;

(b) the MDB shall issue following types of certificates of permission to local manufacturers of medical devices, namely:—

(i) certificate to outsource manufacturing processes of medical devices; and
(ii) certificate to outsource for analysis of medical devices.

(c) the application for certificate under sub-rule (2) shall be made on Form-1(A) or Form-1(B), as the case may be, to the Secretary or Chairman MDB and the outsourcing permission certificate shall be issued on Form-3(A) and Form-3(B);

(d) an application for certificate under sub-rule (2) shall be accompanied with the following, namely:—

(i) application fee as specified in Schedule C; and
(ii) all documents or information as specified in Form-1(A) or Form-1(B), as the case may be.

(e) an application for certificate of permission shall comply with the requirements as specified in these rules;

(f) the MDB may reject an application if the applicant fails to deposit specified fee or provide information, particulars or documents as required under clause (d) of sub-rule (2) and shall inform the applicant of its decision in writing with reasons specified;

Provided that the Authority may, on the recommendations of the MDB, amend the Schedule F so as to omit any entry therefrom, add any entry thereto or amend any entry therein.";

(12) in rule 71, in sub-rule (3), after the word "Organization", the expression "or CE marked by conformity assessment bodies (CABs) notified in NANDO database under the relevant European directive for medical devices subject to evidence and supporting documents" shall be inserted;

(13) in rule 72, in sub-rule (1),—

(a) after the word "The", the word "registered" shall be inserted;

(b) after the word "imported", the word "commercially" shall be inserted; and

(c) for the words "an indenter registered by the MDB", the words "indenting under conditions to be determined by the MDB" shall be substituted.;

(14) after rule 74, the following two new rules shall be added, namely,—

"**75. Emergency use authorization.—** The MDB may grant emergency use authorization to medical devices in public health emergency, national disaster, natural calamity or pandemic, as the case may be, subject to such procedure,

conditions and validity, as may be determined by the Authority on the recommendations of the MDB.

"**76. Regulation for refurbished medical devices.—** Refurbished medical devices shall be regulated as per procedure and standards as may be prescribed by the regulations.";

(15) after Form-1, the following new Form-1(A) and Form-1(B) shall be inserted, namely.—

"DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-1(A)
[See rule 67(2)]

APPLICATION FORM FOR GRANT OR RENEWAL OF CERTIFICATE TO OUTSOURCE MANUFACTURING PROCESSES 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 manufacturing process(es) of medical device(s) to ..... (name of contract acceptor) for the following activities (1).....(2).....

Sr.	Description	Particular
1.	**Purpose of application, whether;**	**Please select appropriate column**
(i)	Fresh/New Application	
(ii)	For renewal of permission certificate to outsource manufacturing processes of medical devices	
	a. Certificate number and date of issue:	
	b. Validity date:	
	c. Last renewal date and its validity:	
	d. 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)	
2.	**Proof of fee deposited:**	
3.	**Contract** between contract giver and contract acceptor (provide on stamp paper duly signed by both)	
4.	**Contract giver details**	**Please provide detail against each**

				where applicable
(i)	Establishment name, address, contact information; (Attach copy of ELM or DRAP Diary No. of Form-1 application)			
(ii)	Details of medical device(s) for which outsourcing is intended to be performed			
(iii)	Details of manufacturing process(es) of each device(s) for which outsourcing is intended to be performed			
5.	**Contract acceptor details**			
(i)	Establishment name, address, contact information			
(ii)	(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)			
(iii)	Names of proprietor/partners/directors; (Also attach readable copies of CNIC)			
(iv)	Residential addresses of partners/proprietors/directors			
(v)	Details of procedure for performing the outsourcing step(s),			
(vi)	Materials to be used			
(vii)	Standards applied (if any).			
(viii	Copy of quality certificates such as ISO13485 etc (if any)			
(ix)	Details of equipment and machinery for manufacturing and instruments for quality control;			
Sr.No.	Name of Equipment	Make	Model	Capacity
(1)	(2)	(3)	(4)	(5)
(x)	In case manufacturing involves biological material then provide the list of all materials of animal, human, microbial or recombinant origin used in product and in the manufacturing process, which includes animal or human cells, tissues or derivatives, rendered non-viable cells, tissues or derivatives of microbial or recombinant origin; the details concerning selection of sources/ donors; harvesting, processing, preservation, testing and handling of tissues, cells and substances;			
(xi)	Expertise available, their qualification and experience (provide names,			

	CNIC(s), degree/certificate, experience letter(s) etc)	
6.	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.

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
1.	**Purpose of application, whether;**	**Please select appropriate column**
(iii)	Fresh/New Application	
(iv)	For renewal of permission certificate to outsource manufacturing processes of medical devices	
	e. Certificate number and date of issue:	
	f. Validity date:	
	g. Last renewal date and its validity:	
	h. 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)	
2.	**Proof of fee deposited:**	
3.	**Contract** between contract giver and contract acceptor (provide on stamp paper duly signed by both)	
4.	**Contract giver details**	**Please provide detail against each where applicable**
(i)	Establishment name, address, contact information; (Attach copy of ELM or DRAP Diary No. of Form-1 application)	
(ii)	Details of medical device(s) for which outsourcing is intended to be performed	
(iii)	Details of analysis processes of each device(s) for which outsourcing is intended to be performed	
5.	**Contract acceptor details**	
(i)	Establishment name, address, contact information	
(ii)	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)	
(iii)	Names of proprietor/partners/directors; (Also attach readable copies of CNIC)	
(iv)	Residential addresses of partners/proprietors/directors	

(v)	Details of procedure for performing the outsourcing step(s),	
(vi)	Details of all the tests to be performed including acceptance limit/criteria	
(vii)	Materials to be used	
(viii)	Standards applied (attach copies of standards)	
(ix)	Analysis/testing protocols to be used (software validation protocol in case of active medical device testing),	
(x)	Copy of quality certificates such as ISO13485 etc (if any)	
(xi)	Details of equipment/facility for performing the tests;	

Sr.No.	Name of Equipment	Make	Model	Capacity
(1)	(2)	(3)	(4)	(5)

(xi i)	Sample report/certificate that will be provided to contract giver upon completion of analysis
(xi ii)	Expertise available, their qualification and experience (provide names, CNIC(s), degree/certificate, experience letter(s) etc)
6.	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.";

(16) after Form-3, the following new Form-3(A) and Form-3(B) shall be inserted, namely.—

"DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-3(A)
[See rule 67(2)]

OUTSOURCING PERMISSION CERTIFICATE FOR MANUFACTURING PROCESSES OF MEDICAL DEVICES

Certificate No. _____
ELM No. _____
Date of issue: _____
File No. _____

M/s ..... (name and address) is hereby certified to outsource manufacturing process(es) of medical device(s) at the following premises .....(name and address)

2. This certificate permit the outsourcing of manufacturing process(es) namely ..... of following medical device(s) .....

3. This certificate shall, in addition to the conditions specified in the Medical Devices Rules, 2017 made under the DRAP Act, 2012, be subject to the following conditions namely:—

(a) The certificate shall be in force for a period of five years from the date of issue unless earlier suspended or cancelled.

(b) The final release of the finished medical device shall be issued by the establishment license holder.

Renewal Date: _____

Secretary,
Medical Device Board
Seal:

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-3(B)
[See rule 67(2)]

OUTSOURCING PERMISSION CERTIFICATE FOR ANALYSIS OF MEDICAL DEVICES

Certificate No: _____
ELM No: _____
Date of issue: _____
File No. _____

M/s ..... (name and address) is hereby certified to outsource analysis of medical device(s) at the following premises ..... (name and address)

2. This certificate permit the outsourcing of analysis namely ..... (name of tests) of following medical device(s) .....

3. This certificate shall, in addition to the conditions specified in the Medical Devices Rules, 2017 made under the Drug Regulatory Authority of Pakistan Act, 2012, be subject to the following conditions namely:—

(a) The certificate shall be in force for a period of five years from the date of issue unless earlier suspended or cancelled.

(b) The final release of the finished medical device shall be issued by the establishment license holder.

Renewal Date: _____

Secretary,
Medical Device Board
Seal:";

(5) in Schedule C, in the Table, in column (1), after serial No. 8 and entries relating thereto in column (2), (3) and (4), the following new serial No. and corresponding entries relating thereto shall be added, namely,—

"9.	OUTSOURCING	Fee for certificate to outsource manufacturing processes of medical devices for each contract acceptor	50,000
		Fee for certificate to outsource analysis of medical devices for each contract acceptor.	50,000
		Fee for renewal of certificate to outsource manufacturing processes of medical devices for each contract acceptor	25,000

		Fee for renewal of certificate to outsource analysis of medical devices for each contract acceptor.	25,000
		Note: Fee for change in particulars of certificate shall be fifty percent of the initial fee of certificate."; and	

(17) after Schedule E, the following new Schedule shall be added, namely,—

"SCHEDULE F

1. The Contract.-- A contract shall be a written agreement which should be drawn up and accepted between the contract giver and the contract acceptor specifying their respective responsibilities relating to the manufacture and/or analysis as under:-

(a) technical aspects of the contract should be drawn up;

(b) all arrangements for manufacture and/or analysis must be in accordance with the conditions of registration or enlistment granted by MDB and agreed by both parties;

(c) the contract should specify the way that each batch has been manufactured and/or analyzed for compliance with the requirements of registration or enlistment;

(d) the contract should describe clearly who is responsible for purchasing materials, testing and releasing materials;

(e) in the case of contract analysis, the contract should state whether or not the contract acceptor should take samples at the premises of the manufacturer;

(f) manufacturing, analytical and distribution records, and reference samples should be kept by or be available to the contract giver. In the event of complaint or suspected defect, any record relevant to assessing the quality of a product must be accessible and specified in the recall procedure of the contract giver; and

(g) the contract should permit the contract giver to visit the facility of the contract acceptor.

2. Contract Acceptor.-- The contract acceptor shall be a person performing manufacturing processes and/or analysis outsourced by the establishment licence holder and is responsible for the following, namely:-

(a) to successfully carry out the work outsourced under the contract by the contract giver;

(b) to have adequate premises and equipment, knowledge and experience, and competent personnel to satisfactorily carry out the work given by the contract giver;

(c) to ensure that all products or materials delivered to him are suitable for their intended purpose; and

(d) not to pass any of the work entrusted to him under the contract to a third party and to refrain from any activity which may adversely affect the quality of the product manufactured or analyzed for the contract giver.

3. Contract Giver.-- The contract giver shall be a person possessing establishment licence and is responsible for the following, namely:-

(a) to assess the competence of the contract acceptor to successfully carry out the work assigned under the contract;

(b) to provide the contract acceptor with all the information necessary to carry out the contracted operations correctly in accordance with the requirements of registration or enlistment and legal requirements;

(c) to ensure that the contract acceptor is fully aware of challenges associated with the product or the work which might pose a hazard to his premises, equipment, personnel, other materials or other products;

(d) to ensure that all processed products and materials delivered to him by the contract acceptor comply with their specifications;

(e) to undertake major steps of production as determined by MDB, including but not limited to the final assembling and packing;

(f) to perform in-process controls;

(g) to keep samples for reference and analysis, if required;

(h) to keep records relevant to assessing the quality of a product in an event of complaint or a suspected defect or recall;

(i) to recall the expired, spurious, substandard, misbranded, counterfeit medical devices as defined by these rules; and

(j) to release the product for marketing upon the test/analysis results carried out by the contract issue final quality control report depending upon the test/analysis results carried out by the contract acceptor in case of outsourcing of analysis.

4. Outsourcing Permission Certificate.-- Outsourcing Permission Certificate means a certificate issued by MDB under sub-rule (2) of rule 67.

5. Procedure for grant of certificate.-- (1) Upon receipt of an application on Form-1(A) or Form-1(B) for certificate, the MDB shall consider the application and shall inspect the premises of outsourced facility to verify any information, particulars, documents and other requirements under these rules. For this purpose, the MDB may also constitute a panel of experts, which may include inspector or auditors;

(2) If satisfied with all requirements under sub-rule (2) of rule 67, including satisfactory inspection report of the premises, the MDB shall issue a certificate to outsource manufacturing processes of medical devices and/or certificate to outsource analysis of medical devices in Form-3(A) or Form-3(B), as the case may be.

(3) A certificate issued under these rules shall, unless earlier suspended or cancelled, be valid for a period of five years from the date of issuance.

(4) Contract giver shall comply with conditions of certificate.

(5) Contract acceptor shall comply with relevant conditions of certificate.

(6) If contract acceptor and/or contract giver does not comply with sub-rule (2) of rule 67, the certificate may be cancelled or suspended as the MDB may deem fit after providing the certificate holder an opportunity of being heard.

(7) The certificate issued to an establishment shall remain the property of the MDB and shall within fourteen days after its cancellation, be surrendered to it without demand.

(8) An application for renewal of certificate shall, sixty days before its expiry, be made to the MDB on Form-1(A) or Form-1(B), as the case may be, and shall be accompanied by the following, namely:—

(a) application fee as specified in Schedule C; and

(b) documents or information specified in Form-1(A) or Form-1(B), as the case may be.

(9) The MDB may reject an application if the contract giver fails to deposit specified fee or provide information, particulars or documents as required under sub-rule (2) of rule 67.

(10) Upon receipt of the application for renewal of certificate, the MDB shall consider the application and may inspect the premises as it considers necessary to verify information, particulars, documents and other requirements under these rules. For this purpose, the MDB may also constitute a panel of experts which may include inspectors or auditors.

(11) If satisfied with all the requirements including satisfactory inspection report of contract acceptor, the MDB may approve renewal of certificate for a further period of five years from the date of expiry of previous certificate unless earlier cancelled or suspended by the MDB.

(12) If an application for renewal is made after expiry of the period of validity of certificate, the applicant shall deposit an additional fee equivalent to applicable renewal fee for each month till one year of the expiry of the certificate and after one year the certificate shall cease to exist and the application shall be treated as a fresh application for issuance of certificate.

(13) If an application for renewal is made before the expiry of the period of validity of certificate or after expiry of the period of validity along with additional fee, the existing certificate shall continue to be valid until orders are passed on such application.

(14) If an application for renewal is made after one year of expiry of the period of validity, the contract giver and contract acceptor shall be responsible for all the illegal operations carried out during that period.

(15) In case the application for renewal of certificate is rejected by the MDB as per procedure laid down under sub-rule (3) of rule 67, it shall inform the applicant of its decision in writing with reasons of such decision.

(16) Where the MDB decides to renew an existing certificate, the renewal of certificate shall be granted on Form-3(A) or Form-3(B), as the case may be.

6. Conditions for issuance of certificate.— The following shall be conditions for issuance of certificate, namely:—

(a) the contract acceptor shall be in possession of such premises which shall be suitable for intended use in size and construction and shall be located in an appropriate area;

(b) the contract acceptor shall provide adequate space, plant and equipment for the manufacturing operations and the analysis facilities including equipment, instruments, space and documentation, as the case may be;

(c) the manufacturing and/or analysis by the contract acceptor shall be conducted under the active directions and personal supervision of competent technical staff as determined by the MDB;

(d) the contract giver shall establish an independent quality control department and maintain separate staff and adequate laboratory equipment for carrying out tests, partial or full, as the case may be;

(e) the contract giver and acceptor shall have an appropriate system of quality assurance for the intended medical devices;

(f) the applicant shall comply with the provisions of DRAP Act and these rules;

(g) the contract acceptor shall provide,—

(i) adequate facilities for first aid and firefighting;

(ii) medical inspection of workers at the time of employment and periodical checkup thereafter at least once a year;

(iii) facilities for vaccination and inoculation against the enteric or any other epidemic group of diseases; and

(iv) adequate precautions for safe-guarding the health of workers, including measures to avoid industrial accidents or diseases;

(h) a contract acceptor who for any purpose is engaged in the culture or manipulation of pathogenic spore bearing micro-organisms shall provide separate laboratories, utensils and apparatus required for the culture or manipulation of such micro-organisms and they shall not be used for the manufacture of any other product;

(i) any change in the expert staff or significant alteration in the premises allowed as contract acceptor or equipment or instrument shall take place in accordance with these rules;

(j) the certificate holder shall, on demand, furnish to the MDB or to such authority as the MDB may direct, from every batch or lot of a medical device, or from such batch or batches of medical devices as it may from time to time specify, a sample, where applicable, for examination and, if required, furnish full protocols of the tests which have been applied;

(k) the certificate along with the licence and the legal agreement shall be kept in the certified premises and shall be produced on the request of any member of the MDB or the concerned Inspector;

(l) the contract acceptor shall allow any member of the MDB or an Inspector to enter the premises and to inspect the plant and the process of manufacture and /or analysis and the means employed in either of the processes and to take samples, where applicable, for test and analysis;

(m) the contract giver and acceptor shall on being informed by the MDB that any part of any batch or lot of a medical device has been found non-conforming with the requirements of these rules, withdraw the remainder of the batch or lot of such device from sale and, as the case be practicable, recall and dispose of all issues already made from that batch or lot in such manner as may be directed by the MDB;

(n) the contract acceptor shall record the particulars of manufacture of each batch or lot of the medical devices manufactured by him and shall retain such records; and

(o) the contract acceptor shall ensure that,—

(i) any unhygienic practices such as eating and smoking shall not take place in any production or quality control area;

(ii) sufficiently clean, appropriately ventilated toilet facilities, including facilities for washing and room for changing clothes, shall be available for the use of manufacturing personnel where required;

(iii) high standard of personnel hygiene shall be observed by all persons concerned with production processes; and

(iv) no person known to be suffering from communicable disease or to be a carrier of such a disease and no person with open lesions or skin infection shall be engaged in production areas.

7. Extent of Outsourcing.— (1) In case of manufacturing, the contract giver will undertake major steps of production as determined by MDB but not limited to the final assembling and packing; and

(2) In case of analysis, the contract giver will perform in-process controls and performance evaluation, as determined by MDB.

8. Changes concerning certificate.— (1) Certificate holder shall apply to MDB for prior approval, if any change is proposed regarding the particulars provided in the certificate.

(2) Application under sub-rule (2) of rule 67 for change in particulars made on Form-1(A) or Form-1(B), as the case may be; and accompanied by the relevant application fee specified in Schedule C.

(3) Upon receipt of the application under sub-rule (2) of rule 67, the MDB shall consider the proposed change and may inspect the establishment through a panel of experts or any inspector or officer authorized by the MDB to verify the particulars, information or documents as provided by the establishment and the

proposed change shall not take effect until the MDB has given its approval for the change.

9. General Responsibilities and Obligations.— (1) Contract giver and contract acceptor shall conduct their operation in accordance with the provisions of these rules and shall comply with the conditions of enlistment or registration issued by MDB and if required by the MDB or its authorized officer, the licensee and enlistment or registration holder shall—

(a) produce the certificate, licence, certificate of enlistment or registration, as the case may be, and

(b) produce such information, documents or samples, in relation to the compliance with the requirements of these rules.

(2) A contract giver who contravenes sub-rule (2) of rule 67 shall, without prejudice to the power of the MDB to suspend or cancel his licence or enlistment or registration, is also guilty of an offence and shall on conviction be punishable under the Drug Regulatory Authority of Pakistan Act, 2012.

(3) Any letter written to the Authority or MDB by the licensee, certificate holder, enlistment or registration holder shall be signed by the proprietor or chief executive officer or managing director or director of the contract giver or firm or organization, including the name, designation and complete address with stamp and, in case of authorized officer in this behalf, shall also be accompanied by the letter of his authorization.".

[No. F.10-1/2020-MD(Vol-I)]

AAMAR LATIF,
Deputy Director (Legal Affairs).

The Manager,
Printing Corporation of Pakistan Press,
Islamabad.