CHECK LIST FOR GOOD STORAGE PRACTICES FOR MEDICAL DEVICES.
Medical Devices and Medicated Cosmetics, DRAP, Islamabad.

Name of the Establishment_____

Address _____

Category of Medical Devices to be imported_____**(Annex List)**

Sr.#.	**Description**	**Compliance**	
		Yes	**No**
PREMISES DETAILS			
1.	Is the storage facility appropriate in terms of floor, walls, roof, ventilation, entrances and exit gates? (e.g. Appropriate covering and maintenance of flaking, corrosion, rust, openings of door-ways/vents, drains, ingress of pests/rodents etc.)		
2.	Are SOPs, Checklist & working instruction's for personnel safety placed?		
3.	Is there an appropriate system in-place for encountering any emergency/ accidental situation.? (e.g. Appropriate firefighting equipment, smoke alarms, etc. and the SOPs and working instructions are placed.)		
4.	Is there a scheduled cleaning system in-place alongwith SOPs, Checklist & working instruction's?		
5.	Is there an appropriate system for recording of temperature and humidity in-place?		
6.	Is there an appropriate system in-place for all the machinery, equipment or instruments etc. for standard storage conditions?		

	(Internally biannual calibrations, validation or maintenance while externally it is required on annual basis.)		
7.	Is alternate source of electricity available for continuous provision of standard storage conditions?		
8.	Whether there is proper inventory control, record and management systemin-place?		
9.	Is there awarranty system established as per MDR, 2017.? (Warranty shall only be passed by qualified person and proprietor.)		
10.	Is there any SOPs and record management system in-place for any outsource activity? (External audit system, calibration, transportation etc.)		
11.	Has the importer hired (on permanent basis) a qualified/technical Staff like Pharmacist, Bio-medical engineer, Software engineer, Biotechnologist, Medical Lab Technologist, Microbiologist, Bachelor of Veterinary sciences, Biochemist, Medical or Bio-physicist or Software technologists as per MDR, 2107 (in accordance to products category) to manage the appropriate storage? Name: _____Qualification: _____ Registration No.:_____ Validity:-_____		
POST MARKET SURVEILLANCE SYSTEM		**Compliance**	
		Yes	**No**
12.	Has the importer established a complaint handling system? (Includes SOPs & Checklists).		
13.	Has the importer established a Corrective and Preventive action (CAPA) mechanism? (Includes SOPs, Checklists & working instructions).		
14.	Has the importer established a Field Corrective and Field safety mechanism? (Includes SOPs & Checklists).		
15.	Has the importer established the Re-Call system of Medical Devices? (Includes SOPs, Checklists & working instructions).		
FOR SPECIALIZED TEMPERATURE SENSITIVE MEDICAL DEVICES.			
Sr.#.	**Description**	**Compliance**	
		Yes	**No**

16.	Is there an appropriate cold chain mechanism between all channels of supply (manufacturer-importer-Distributor/Hospital/Retailer/End User) of cold storage medical maintained? (Includes SOPs/ Guidelines, Checklist.)		
17.	Has the importer established a record management system of authorized distributor those ensure the cold chain system to retailer and consumer?		

Any Comments/ note of Inspector(s):	
Name & Designation of Firm representative(s) present at the time of inspection.	

Final remarks: **-Recommended/Not Recommended.**

Sr.#.	**Name of Inspector**	**Designation**	**Signature&Date**
1.			
2.			

List of documents to be maintained by importer: -

1. Site master file (Establishment details, owners' detail, product portfolio and complete record management of all the steps of import and distribution of medical devices).
2. Documented job descriptions of all workers and its compliance.
3. SOP for import or purchase, storage and issuance of Medical Devices.
4. SOP for sudden/accident condition handling and its investigation by manufacturer, health regulatory authority and importer itself (product specific or whole storage facility).
5. SOP for return and disposal of medical devices.
6. SOP for handling of Spurious, Sub-standard, False-labelled, Falsified and Counterfeit (SSFFFC) and Expired, Rejected and Damaged (ERD) etc. Medical Devices.
7. SOP for personnel training &hygiene.
8. SOP for environmental control.
9. SOP for labeling/ relabeling of medical devices (for printing of license details, etc.).
10. SOP for installation and service providing for maintenance of medical devices, if applicable.
11. SOP for management of accessories, components or parts of medical devices.