CHECK LIST FOR GOOD DISTRIBUTION PRACTICES FOR MEDICAL DEVICES

Name of the importer/ distributor_____

Address _____

_____

List of Medical Devices intended to be imported _____

_____

Sr.No.	Description	Compliance	
		Yes	No
PREMISES DETAILS			
1.	Are surfaces free of flaking paint, corrosion, rust and other materials (eg., tape, Woods etc?		
2.	Checklist for personal safety		
3.	Are openings to doorways, vents, and drains covered to prevent the ingress of pests, etc.		
4.	Is there a smoke alarm and firefighting equipment available.		
5.	Is it clear from any rubbish.		
6.	Is floor clean from water.		
7.	Is there a cleaning schedule in place for store and surrounding?		
8.	Is there a procedure for pest control monitoring and treatment		
9.	Is there any signs of vermin such as cockroaches, mice, rats, and bats.		
10.	Check temperature record.		
11.	Has all recording and monitoring equipment been calibrated in the last year		
12.	Is standby generator/UPS available		
13.	Is there any routine and emergency maintenance plan?		
INVENTORY AND RECORD MANAGEMENT			
14.	Whether there is proper inventory control system		
15.	Are all the products are properly placed or arrangements are made for systematic storage.		

16.	Is their warranty system established		
OUTSOURCE ACTIVITIES			
17.	Check if there is any maintenance agreement with an outside agency.		
18.	Is routine maintenance being performed correctly at the intervals stated in the agreement		
TECHNICAL STAFF AND DRUG SALE LICENCE DETAILS			
19.	Does the importer have hired qualified Technical Staff (Pharmacist, Bio-medical engineer, Software engineer, Biotechnologist, Medical Lab Technologist, microbiologist, veterinary sciences, biochemist, medical physicist or bio physicist, or software technologists) to manage the proper storage		
20.	If the answer of above question is yes then what is the name and registration number of the qualified technical staff (also attach copy of the DSL) Name_____ Registration No._____ DSL Number_____ Validity:-_____		
POST MARKET SURVEILLANCE SYSTEM			
21.	Does the importer have established the Re-Call system of Medical Devices ?		
22.	Does the importer have established a Complaint Handing system?		
23.	Does the importer have established a Corrective and Preventive action (CAPA) mechanism?		
24.	Does the importer have established a Field Corrective and Field safety mechanism?		
FOR SPECIALIZED TEMPERATURE SENSITIVE MEDICAL DEVICES (IF APPLICABLE)			
Sr.No.	**Description**	**Compliance**	
		Yes	**No**

1.	Check weather the cold chain is established from manufacturer to the importer (For specialized products).		
2.	Is there a mechanism for the cold chain from manufacturer to the importer?		
3.	Is there any cold storage system at the Air Port/Sea-port/Dry Port.		
4.	Does the firm have special vehicle for distribution of temperature sensitive Medical Devices.		
5.	Does importer ensured the cold chain establishment from their distributor to the retailer/ consumers		
6.	Does the importer have documentation and list and list of authorized distributor who ensure the cold storage and cold chain onward to retailer and consumer?		
7.	Does the importer developed guidelines to ensure the cold storage and cold chain facility till the end consumer		

Any Comments _____

Final remarks: - Please Fill the relevant Box.

Recommended ☐ **Not Recommended.** ☐

Sr. No.	**Name of Inspector**	**Designation**	**Signature**	**Date**
1.				
2.				

3.				
4.				

Reference:- Good Distribution practices for Medical Devices MDB/GD No.2 dated September, 2016

List of Documents required:-

1. Site Master File (Establishment details, Owners detail, product portfolio, etc) .
2. Job descriptions of all workers.
3. SOP for Import or Purchase of Medical Devices.
4. SOP for Complaint Handling, Corrective and Preventive Action.
5. SOP for Medical Device Re-call.
6. SOP for Incident and Accident Investigation.
7. SOP for Field Corrective and Safety Action, where applicable.
8. SOP for Return and disposal of Medical Devices.
9. SOP for handling of Expired, Spurious, Mis-Branded, Counterfeit etc, Medical Devices.
10. SOP for Internal Audit (i.e inventory, expiry, premises etc).
11. SOP for Personnel Hygiene.
12. SOP for Training (i.e SOP and product related).
13. SOP for Receiving, Storage and Handling of Medical Devices.
14. SOP for Issuance of Medical Devices.
15. SOP for Rejected and Damaged Medical Devices.
16. SOP for Environmental Control.
17. SOP for Handling of medical devices with Special Storage Condition i.e. Temperature Sensitive (if any).
18. SOP for Labeling/ Relabeling of Medical Devices (for printing of Licence Details, etc).
19. SOP for Installation and Service Providing for Maintenance of Medical Devices, where applicable.
20. Work instructions for Handling of Medical Devices during Installation and Servicing, where applicable.
21. SOP for Calibration and Validation.
22. SOP for Management of Spare Parts of Medical Devices.
23. SOP for Outsource Activities.
24. SOP for Cleaning of Area.