

الهيئة الوطنية لتنظيم المهن والخدمات الصحية NATIONAL HEALTH REGULATORY AUTHORITY

Inspection Requirements Form Should by filled by authorized representative		
Address: Co	Contact No:	
 Mandatory Requirements: Office: 1. Tracing system (Software). including LOT no., Batch no., So End user, recalls, complaints. 2. Recalls, complaints and adverse event Forms. 3. Access Control for store. 4. Register with FDA+MHRA+ SFDA, for FSN 5. Labeling for (Damage area-expired Items) 6. Staff should be fully aware of submitted polices 7. Labeling for products. 8. Destruction records in software and hardware. 9. Temperature log (excel sheet registered the date, time tempe 10. Fire extinguisher available and maintained. 		
> Conditional Requirement:	Completed	N/A
Storage space or Store location.		
2. Cold room if needed		
3. UBS / generator in cases of power failure.		
4. Receiving and delivering area.		
I hereby, declare that all the above requirements are fulfilled our company is ready for NHRA inspection. Authorized Person Name: Job Title: Signature:	=	<u>' and</u>
Sta	amp:	

Tel: +973 17 11 33 37 Fax: +973 17 11 32 72 P.O. Box: 11464 , Manama Kingdom of Bahrain E-Mail: medical-device@nhra.bh Website: www.nhra.bh