



## Field Safety Notice Form

*THIS FORM IS INTENDED TO BE USED BY AR TO REPORT A RECIVED FSN TO NHRA*

Report type:     Recall                       Corrective Action                       Alert

Reporter Details	
Reporter issuer	<input type="checkbox"/> Regulatory Authority <input type="checkbox"/> Manufacturer
Regulatory Authority	<input type="checkbox"/> FDA <input type="checkbox"/> SFDA <input type="checkbox"/> MHRA <input type="checkbox"/> GHC <input type="checkbox"/> Swissmedic <input type="checkbox"/> TGA
Report Reference Link (Required)	<b>Link:</b> .....
Copy of Report	<b><u>Attach</u></b>
Manufacturer Details	
Name	
Country of origin	
Email Address	

Medical Device Details <i>( if more than one model / Serial No. / Lot No. please attach list)</i>			
Device Name			
Model No.		Serial No.	
NHRA Medical Device Registration License	<b><u>Attach</u></b> <input type="checkbox"/> N/A	Lot Number	
LPO	<b><u>Attach</u></b>	Importation history	<b><u>Attach</u></b>
Description of FSN			
Advised Action by the Manufacturer			



Authorized Representative Details	
Name	
Email Address	
Telephone No.	
NHRA License No.	
Action Required	
Corrective action	<input type="checkbox"/> Software update <input type="checkbox"/> New IFU <input type="checkbox"/> Spare part replacement <input type="checkbox"/> No Action (Alert Report)
Recall	<input type="checkbox"/> Return to manufacturer <u>Attach Airway Bill</u> <input type="checkbox"/> Destruction in Bahrain <u>Attach invoice destruction</u>

End-user Details	
Healthcare facility Name	
Contact Person	
Email Address	
Acknowledgment	<u>Attach</u>

**I hereby declare that all the above information is correct and accurate, and all the required documents will be submitted within ONE month starting from the date of NHRA receiving the form, and I am fully aware of the consequences of the non-compliance to the time frame set. And I will inform NHRA of any difficulties to implement the action required.**

Authorized Person -----

Signature -----

**\*In case of the electronic stamp and signature are not available, Please provide a declaration letter stating that all the provided information in the above or attached form are correct and authentic.**

**Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.**