



## Recall / FSN Check list

Required Documents	Remark
1. <b>Recall / FSN Form</b>	
2. <b>Official Letter</b> issued from manufacturer in case Bahrain market is not affected by the Recall / FSN.	
3. <b>Copy of Recall / FSN</b> in case the affected medical device is marketed in Kingdom of Bahrain.	
4. <b>End-User Acknowledgment</b> stating the corrective action taken and if there is any adverse event caused by the affected Medical Device.	
5. <b>Airway bill</b> in case of returning affected medical devices to the manufacturer.	
6. <b>Invoice of destruction</b> issued from Bahrain Medical Waste stating the description of the destroyed Medical Devices.	

**Note:** All documents should be submitted within the following time frame:

1. 2 Working days in case of **very high risk** FSN.
2. 5 Working days in case of **high risk** FSN.
3. 10 Working days in case of **moderate risk** FSN.