



Recall / FSN Check list

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

E-Mail: md0047@nhra.gov.bh
MD0047



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公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



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Box: 11464