



Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

| Device Details | | | | | | |
|--------------------------|--|--------|--------|--------|--------|--------|
| Device Name | BD BBL™ Sensi-Disc™ | | | | | |
| Catalogue Number | 231251 | 231539 | 231633 | 231660 | 231682 | 232175 |
| | 231263 | 231544 | 231635 | 231664 | 231692 | 232219 |
| | 231264 | 231607 | 231641 | 231672 | 231696 | |
| | 231274 | 231621 | 231645 | 231674 | 231704 | |
| | 231344 | 231629 | 231658 | 231678 | 231706 | |
| Manufacturer | Becton, Dickinson and Company (BD) | | | | | |
| Country of Origin | USA | | | | | |
| Reference | <u>Link</u> | | | | | |
| | NHRA initiates this FSN due to identifying that BD BBL™ Sensi-Disc™ may produce variable r | | | | | |
| Reason of Alert | for Haemophilus susceptibility testing, leading to potential inaccuracies. | | | | | |
| Action should be | Please refer to "Actions to be taken by Customer/ User" in the attached FSN | | | | | |
| taken | And for more information please contact the authorized representative Wael Pharmacy Co. | | | | | |
| | W.L.L at sharon@waelpharmacy.com | | | | | |

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

For more information please contact Medical_Devices@nhra.bh

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