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:

<table>
<tr><th colspan="2">Device Details</th></tr>
<tr><td>Device Name</td><td>3M Steri-DrapeTM Surgical Drapes</td></tr>
<tr><td>Device Model</td><td>1000,1010,1020, 1021, 1030, 1033, 1060, 1061, 1061NS, 1071</td></tr>
<tr><td>Lot No.</td><td>
<table>
<tr><th>Catalogue number</th><th>Lot number</th></tr>
<tr><td>1000</td><td>33HD8F, 33HDDH, 33HFFJ, 33HX4N, 33HXRF, 33HY4P, 33HYA7, 33J5T7, 33J639, 33J6EN, 33J7X8, 33K3DP, 33K3L9, 33K54E, 33K7J8, 33K8KM, 33KXDH, 33LACE</td></tr>
<tr><td>1010</td><td>33HHC9, 33HHKA, 33HJNT, 33HLXD, 33HYNH, 33J9CP, 33JATF, 33JFDY, 33JJ9P, 33JMKP, 33JMTJ, 33KE9E, 33KJ63, 33KJEX, 33KLNH, 33KM9K, 33KMLN, 33KNXW</td></tr>
<tr><td>1020</td><td>33HD6C, 33HJ3K, 33HLKE, 33HNJ3, 33J43T, 33J5CP, 33J8A7, 33J9RC, 33JD5A, 33JTFX, 33JXRJ, 33K7NF, 33KCX3, 33KL5W, 33KR5C, 33KRDE, 33L6M5</td></tr>
<tr><td>1021</td><td>33H9HW, 33HXMD, 33JKD4, 33JKLL</td></tr>
<tr><td>1030</td><td>33HFW5, 33HH8Y, 33JRFA, 33KKLW, 33KL53</td></tr>
</table>
</td></tr>
<tr><td>Manufacturer</td><td>3M</td></tr>
<tr><td>Country of Origin</td><td>USA</td></tr>
<tr><td>Reference</td><td>http://www.hpra.ie/docs/default-source/field-safety-notices/november-2022/v53040_fsn.pdf?sfvrsn=2</td></tr>
</table>

For more information please contact Medical_Devices@nhra.bh

Reason of Recall	NHRA initiates this FSN due to the fact that the liner on the adhesive component of the affected drapes is difficult to remove without damaging the product and may render the product unusable. Furthermore, there has been an increase in the number of reported adhesive-related skin injuries for these affected lots.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative to take the necessary action for recall.

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

For more information please contact Medical_Devices@nhra.bh