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Medical Device / Equipment **RECALL**

Date Issued : 23rd July 2008

Ref:MDB/R/2008/011

IMMEDIATE ACTION	√
ACTION	
UPDATE	
INFORMATION REQUEST	

PRODUCT	<p>Smiths Medical Portex™ Blue Line Ultra tracheostomy kits, lot no. 499265.</p> <p>Portex™ Blue Line Ultra tracheostomy kit, smooth inner cannula, fenestrated, Orator speaking valve uncuffed 8.0mm ID. Product code: 100/833/080, lot no. 499265.</p> <p>Portex™ Blue Line Ultra tracheostomy change kit, Suctionaid, smooth inner cannula, Soft Seal profile cuff.</p> <p>Product code: 100/880/080, lot no. 499265.</p> <p><i>*refer to reference below for details about this recall</i></p>
CLASS	Not Available
USE	It is a Tracheostomy kits for the ongoing care of adult patients.
SOURCE OF MEDICAL DEVICE RECALL / ALERT	Medicines and Healthcare products Regulatory Agency, United Kingdom's website, Date issued: 22 nd July 2008
ALERTING / RECALLING FIRM	Smiths Medical United Kingdom
REASON	Mislabelling of device may result in the use of a fenestrated suction tube, reducing both suction and ventilation. In the United Kingdom, the manufacturer has recalled all stock supplied directly to NHS

	<p>trusts.</p> <p>However, affected devices have also been distributed via third party suppliers and are not yet accounted for.</p> <p>Blue Line Ultra Suctionaid tracheostomy change kits (product code 100/880/080) from lot 499265 will contain a Blue Line Ultra fenestrated, uncuffed tube.</p> <p>Although this tube will maintain an airway if used, it will reduce ventilation efficiency and will not provide any direct suctioning ability.</p> <p>It is advisable for the distributors or sales representative of the abovementioned companies in Malaysia to respond to this recall notice.</p>
<p>SCENARIO IN MALAYSIA</p>	<p>No details available at this moment. For users, please check whether the device is available and contact the distributor.</p>
<p>ACTION</p>	<p><i>Recommendations For Healthcare Professionals</i></p> <ul style="list-style-type: none"> • Ensure that all relevant staff in your institution are informed of this safety alert/warning • Determine if you have the affected products • Locate and monitor the usage of the affected products • Determine how much of this product has been used • Follow the distributor / manufacturers recommendations for quarantine and disposal of product • Follow up patients as required.
<p>RECOMMENDATION</p>	<p>Users of the abovementioned device should contact the distributors/supplier of this device (if available) and inform the Medical Devices Bureau, Ministry of Health providing the following information:-</p> <ol style="list-style-type: none"> a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available
<p>CONTACT/ENQUIRIES IN MALAYSIA</p>	<p>BUMI T. T. C. (SABAH) SDN BHD Erh-Ling Chang Shop No. 21 & 22, Kepayan Ridge Commercial Centre, Phase 2, Lrg. Bunga Tanjung 2,</p>

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REFERENCES

<http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON020695>