



Medical Devices Bureau, Ministry of Health Malaysia
 Level 5, Block E6, Complex E,
 Federal Government Administrative Centre,
 62590 Putrajaya, MALAYSIA.
 Tel: 03-8883 2248/2249/2264
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Medical Device / Equipment **RECALL**

Date Issued : 3 JULY 2008

Ref:MDB/R/2008/010

IMMEDIATE ACTION	√
ACTION	√
UPDATE	
INFORMATION REQUEST	

PRODUCT	Electrosurgical single-use, sterile blades and needles. ‘Universal’ and ‘Ultraclean’ electrodes manufactured by ConMed.
CLASS	Not Mentioned
USE	Electrosurgical blades
SOURCE OF MEDICAL DEVICE RECALL / ALERT	Medicines and Healthcare products Regulatory Agency, United Kingdom’s website, Date issued: 17 th June 2008
RECALLING / ALERTING FIRM	As in the United Kingdom ConMed Linvatec 73/74 Shrivenham Hundred Business Park Swindon Wiltshire SN6 8TY Tel: 01793 787 912 Fax: 01793 784 568
REASON FOR RECALL/ALERT	A limited number of electrosurgical blades and needles may have an inadequate packaging seal, potentially compromising the sterility of the device (<i>see attachment for list of relevant catalogue and lot numbers</i>).
SCENARIO IN MALAYSIA	No information available at this moment.
ACTION	Users are advised to: <ol style="list-style-type: none"> 1. Identify and quarantine the affected devices mentioned in this notice. 2. Contact the relevant suppliers/distributors (if

	available) of the device for further action.
RECOMMENDATION	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:- <ul style="list-style-type: none"> a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available
CONTACT/ENQUIRIES	Currently No Information Available
REFERENCES FOR DETAILS	<i>http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON018119</i>

Notes:- this notification is forwarded based on the information gathered from the Medicines and Healthcare products Regulatory Agency, United Kingdom (MHRA) website.

Attachment

**URGENT – Voluntary Device Recall
ConMed Electrosurgery**

Catalog numbers and Lot Numbers Affected

Catalog Number	Lot number					
138107	0710191	0710231	0710232	0710241	0710242	0710251
138110	0711011	0711012	0711031			
138112	0711031	0711032	0711033	0711041	0711042	
138113	0711091					
139104ext	0711121					
139107	0710291	0710301	0710302	0710311		
139108	0711091					
139110 ext	0711051	0711052	0711053			
139112	711081	0711082				
139112ext	0711071	0711072	0711073	0711081		