



**Medical Devices Bureau, Ministry of Health Malaysia**  
 Level 5, Plot 3C4,  
 No. 26, Jalan Persiaran Perdana,  
 Precint 3, 62675 Putrajaya  
 Malaysia  
 Tel: 603-8885 0767 / 603-8885 0773  
 Fax: 603-8885 0759

**Medical Device / Equipment ALERT : Device Information**

**Date Issued : 24 AUGUST 2009**

**Ref:MDB/A/2009/006**

<b>IMMEDIATE ACTION</b>	√
<b>ACTION</b>	
<b>UPDATE</b>	
<b>INFORMATION REQUEST</b>	

*\*The dissemination of this information is based on the Important Product Information submitted by Baxter Healthcare (M) Sdn. Bhd.*

<b>PRODUCT</b>	<b>Baxter Infusor– Product Codes: 2C1008KP, 2C1009KP - Multiple lots affected.</b>
<b>CLASS</b>	Not Mentioned
<b>USE</b>	Infusor – for delivering drugs/liquid/solution.
<b>SOURCE OF MEDICAL DEVICE RECALL / ALERT</b>	<b>Attachment(s) from Baxter Healthcare (M) Sdn. Bhd. via electronic mail.</b>
<b>RECALLING / ALERTING FIRM</b>	<b>Baxter Healthcare (M) Sdn. Bhd. Suite 12.01, Level 12 The Gardens, South Tower Mid Valley City, 59200 Kuala Lumpur Malaysia</b>
<b>REASON FOR RECALL/ALERT</b>	<b>- Refer attachment for details-</b>
<b>SCENARIO IN MALAYSIA</b>	Customers have been notified by the responsible representative.
<b>ACTION</b>	<i>*any healthcare facilities possessing the abovementioned device are advised to respond to this communication immediately.</i>
<b>RECOMMENDATION</b>	<b>Users of the abovementioned device <u>should contact the distributors/supplier of this device</u></b> (if available) and inform the Medical Devices Bureau, Ministry of

	<p>Health providing the following information:-</p> <ul style="list-style-type: none"> <li>a. Name of healthcare centre/hospital/clinic</li> <li>b. Contact person and contact number</li> <li>c. Numbers of units available</li> <li>d. Name of the supplier(s)</li> </ul>
<b>CONTACT/ENQUIRIES</b>	<p><b>Ng Yu Seen,</b>  <b>Assistant Manager,</b>  <b>Regulatory Affair</b>  <b>Baxter Healthcare (M) Sdn. Bhd.</b>  <b>Suite 12.01, Level 12</b>  <b>The Gardens, South Tower</b>  <b>Mid Valley City,</b>  <b>59200 Kuala Lumpur</b>  <b>Malaysia</b></p> <p><b>Tel:- 03-22676015</b>  <b>Fax:- 03-22831784</b></p>
<b>REFERENCES FOR DETAILS</b>	<p><b>Notification do includes Important Product Information – which alerted users about hazards associated with improper handling of the device.</b></p>

NOTIFICATION BY MEDICAL DEVICE BUREAU 2009