



## Medical Device Recall Reporting Form - Initial

**Purpose:** To capture the information manufacturers and importers are required to report to Health Canada on or before undertaking a recall, as per S. 64 of the *Medical Devices Regulations*. Refer to the [Guide to Recall of Medical Devices \(GUI-0054\)](#) for more information. The personal information you may provide to Health Canada is governed in accordance with the *Privacy Act* and is collected to administer the Medical Device Compliance and Enforcement program authorized under the *Food and Drugs Act*. This personal information collection is described in Info Source, available online at [infosource.gc.ca](http://infosource.gc.ca). Refer to the personal information bank HC PPU 405. For more information about our privacy practices, please contact the Privacy Management Division - Director at 613-355-1458 or [Privacy-vie.privee@hc-sc.gc.ca](mailto:Privacy-vie.privee@hc-sc.gc.ca). For any other questions, please contact the appropriate regional office, as identified at the end of this form. Use of this form is optional. All information collected on this form will be treated as confidential business information.

**Submitter Type:**

**If an importer, are you reporting on behalf of the manufacturer?**

<b>64 (a) the name of the device and its identifier</b> (including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group)	
Name of device(s):	Identifier(s):
Other device-related information: (eg. Licence #, device I.D., etc.)	

<b>64 (b) the name and address of the manufacturer and importer</b> (and the name and address of the establishment where the device was manufactured, if different from that of the manufacturer)	
Manufacturer(s):	
Importer(s):	

<b>64 (c) the reason for the recall</b> (the nature of the defectiveness or possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered) <b>(Please limit to 50 words or less and provide translation-validated text in both English and French).</b> <i>Note: Add additional information as attachments</i>

<p><b>64 (d) An evaluation of the risk</b> (associated with the defectiveness or possible defectiveness)  <i>Note: Add additional information as attachments</i></p>

<b>64 (e) the number of affected units of the device that the manufacturer or importer:</b>	
manufactured in Canada:	
imported into Canada:	
sold in Canada:	

<b>64 (f) the period during which the affected units of the device were distributed in Canada by the manufacturer or importer</b>			
From date:		To date:	
yyyy-mm-dd		yyyy-mm-dd	

<b>64 (g) the name of each person to whom the affected device was sold by the manufacturer or importer and the number of units of the device sold to each person</b>	
<i>Note: Enter information below or attach list of consignees and the number of units sold to each</i>	
Name of Each Consignee:	Number of Units Sold to each consignee:

<p><b>64 (h) a copy of any communication issued with respect to the recall</b>  <i>Note: Add additional information as attachments</i></p>

<b>64 (i) the proposed strategy for conducting the recall</b> (including the date for beginning the recall, information as to how Health Canada will be informed of the progress of the recall and the proposed date for its completion) <i>Note: Add additional information as attachments</i>	
Recall start date:	yyyy-mm-dd
Proposed completion date:	yyyy-mm-dd
Strategy:	
<b>64 (j) the proposed action to prevent a recurrence of the problem</b> <i>Note: Add additional information as attachments</i>	

<b>64 (k) the name, title and telephone number of the representative of the manufacturer or importer to contact for any information concerning the recall</b>	
Name:	
Title:	
Telephone Number:	
Email Address:	

<b>Other relevant information concerning the recall, if any</b> <i>Note: Add additional information as attachments</i>

# Health Canada Contacts for Reporting Medical Devices Recalls

Notification of recall is submitted to the appropriate Region. Companies that do not know under which Region they fall, can contact the Regulatory Operations and Region Branch at: 1-800-267-9675

<p><b>@WUjcb'cZF YWU`jbl` : jfa`</b></p>	<p><b>F YWU` F Ydcfjhb[ '5 XXfYgg'</b></p>
<p><b>7 UbUXU.</b> Á^ ÁÓi` } • Æ È^, {` } á æ á/æ á/æá æá [ :ÈÁ P[ çæÁU&amp; çæÁU á &amp; ÁÓá, æáÁQ æ) áÁ G5.ÁÓ[ ] } ^ &amp; çæ` çÁ Ö æ) æ^ ÈÁ æ) ^ ÈÁ æ`  æ) á ÈÁ æ • æ@ • ^ ç È^, Á Pæ ] • @^ È^, ÁR • ^ ÈÁ @ á^ ÁQ æ) á ÈÁ^   [ ] á <b>K cf X.</b> Á áá  ÁÓæ á Qæ çæ ÈÓ ] i` • ÈQæ ÈQæ ÈQæ   ÈÁ R   áæ ÈS` , æ ÈS^ áæ [ ] ÈÁ { æ ÈÁ æ ÈÁ æ ááQæ ááÁ Syria, Turkey, United Arab Emirates, West Bank and Gaza Strip, Yemen)</p>	<p><b>5 hUbhWF Y[ ]cb.</b> T^ ÁáæçÁÖ` çæ^ Á Ó[ { ]  æ) &amp; ÁU  ` *  æ ÈÁ` æ ÁFÍ G ÈFÍ °Á Q[ [ ] ÈFÍ ÈÍ ÁÓæ á * ç } ÁUd^ ÁP çæçÈÁ P[ çæÁU&amp; çæÁU ÁYÍ Á ÚQ) ^ ÁUÈÈÍ G ÈFÍ È ÇæÁUÈÈÍ G ÈÍÍÍ Á Ò( æÁ <a href="#">UVŠÈ ÖÖO PÔÈÛÔÈÖÈÖÁ</a></p>
<p><b>Canada:</b> Quebec  <b>USA:</b> District of Columbia, Florida, Georgia, New York, North Carolina, Pennsylvania, South Carolina, Virginia, West Virginia  <b>World:</b> All islands in the Caribbean, Central America (Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama), Scandinavia and Baltic States (Denmark, Estonia, Finland, Latvia, Lithuania, Norway, Sweden), Central Europe (Austria, Belgium, France, Germany, Liechtenstein, Luxembourg, Netherlands, Switzerland)</p>	<p><b>E i VYWF Y[ ]cb.</b> T^ ÁáæçÁÖ` çæ^ Á Ó[ { ]  æ) &amp; ÁU  ` *  æ ÈÁÈÈÁU` ^ ÁUÈ Šæ   ^) ÁU` ^ • çS[ ] * ^ ç ÈÁ` ^ á^ &amp; Á R SÁÖÍ Á ÚQ) ^ ÁUÍ ÈÈÍ Í ÈFÍ HÁ ÇæÁUÍ ÈÈÍ G È ÈÍ Á Ò( æÁ <a href="#">UWÈÈ ÖÖO PÔÈÛÔÈÖÈÖÁ</a></p>
<p><b>Canada:</b> Ontario  <b>USA:</b> Alabama, Illinois, Indiana, Kentucky, Michigan, Mississippi, Ohio, Tennessee, Wisconsin  <b>World:</b> Northern Europe (Iceland, Ireland, England, Scotland, Wales, Northern Ireland), Eastern Europe (Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Serbia, Slovak Republic, Slovenia), Southern Europe (Greece, Holy See, Italy, Malta, Monaco, Portugal, San Marino, Spain), all countries in South America</p>	<p><b>CbHU]c F Y[ ]cb.`</b> T^ ÁáæçÁÖ` çæ^ ÁÓ[ { ]  æ) &amp; ÁU  ` *  æ ÈÁ GÈFÁ á æ) á ÁQ^ ÈÁV[ : [ ] ç ÈÁ } çæ) ÈÁ T FÚÁ ÚÍ Á ÚQ) ^ ÁUÍ FÍ ÈÍ ÈFÍ ÈÈÁ ÇæÁUÍ FÍ ÈÍ Í ÈÍ Í FÁ Ò( æÁ <a href="#">UVVÈ ÖÖO PÔÈÛÔÈÖÈÖÁ</a></p>
<p><b>Canada:</b> Manitoba, Saskatchewan  <b>USA:</b> Arkansas, Iowa, Kansas, Louisiana, Minnesota, Missouri, Nebraska, North Dakota, Oklahoma, South Dakota, Texas  <b>World:</b> All countries in Africa, Mexico</p>	<p><b>A Ub]c VU!GÜg_ UHW Yk UbF Y[ ]cb.`</b> T^ ÁáæçÁÖ` çæ^ ÁÓ[ { ]  æ) &amp; ÁU  ` *  æ ÈÁ FÈÈÁU FÁ [ : \ ÁQ^ ) ^ Á á } á ^ ÈÁ ÓÁÁ ÜHÓÁ Y FÁ ÚQ) ^ ÁUÈÈÍ ÈÍ ÈÍ ÈÍ F ÇæÁUÈÈÍ ÈÍ ÈÍ FÍ HÁ Ò( æÁ <a href="#">UÈÈ ÖÖO PÔÈÛÔÈÖÈÖÁ</a></p>

