

## **Major Safety Alerts in January 2010 (This page is subject to further review)**

The following safety alerts has a reasonable chance that the product will cause serious health problems or death. These cases will be forming part of the summary of January 2010 and more details will be provided when available

\*Note: FDA = Food and Drug Administration, United States of America; MHRA = Medicines and Healthcare products Regulatory Agency, United Kingdom; Health Canada = Health Canada, Canada

Description of Product	Source of Information*	Reference No. by Source	Alert Type by Source	Date of Issue (YYYY/MM/DD)	Local Agent	Agent Contact Telephone No.
ev3 Trailblazer Support Catheter (Model no. SC-014-135, SC-018-090, SC-035-065, SC-035-135, SC-014-150, SC-018-150, SC-035-090, SC-035-150)	<a href="#">FDA</a>	N.A.	Class I	2010/01/06	Sinomed Company Ltd.	2887 7640
Merit Medical Systems Mistique Infusion Catheters	<a href="#">MHRA</a>	2009/012/030/081/016	FSCA	2010/01/14	King Health Limited	2481 3787
Philips Heartstart FRx AED (861304) and Heartstart HS1 Onsite Defibrillator (M5066A)	<a href="#">Health Canada</a>	51902	Type II	2010/01/22	Philips Electronic Hong Kong Ltd	2821 5480
Accuray Cyberknife Robotic Radiosurgery System (MultiPlan Treatment Planning System Version 3.5)	<a href="#">MHRA</a>	2010/001/019/291/012	FSCA	2010/01/25	Accuray Asia Ltd	2247 8628
Hettich Plastic Hematocrit Rotors (201424-01 Haematocrit 20 with 2050 haematocrit rotor, 2004-01 Mikro 20 with 2076 haematocrit rotor, 2070 Mikro 12-24 with 2050 haematocrit rotor, 2075 Haematocrit 24 with 2050 haematocrit rotor)	<a href="#">FDA</a>	N.A.	Press Release	2010/01/25	N.A.	N.A.
Exelint Exelint Exel/Exelint Huber needles (Code: 26901, 26902, 26904, 26906, 26907, 26908, 26909, 26911, 26921, 26922, 26923, 26924, 26925), Exel/Exelint Huber Infusion Sets (Code: 27940R, 27941R, 27944R, 27945R, 27946R, 27948R, 27949R, 27950R, 27954R, 27955R, 27958R, 27959R) and Exel/Exelint "Securetouch+" Safety Huber Infusion Sets (Code: 37854S, 37855S, 37858S)	<a href="#">FDA</a>	N.A.	News Release	2010/01/27	N.A.	N.A.
Edwards Lifesciences Aquarius Hemodialysis System (Model no. GEF08200, GEF09500, GEF09600, GEF09700, and GEF09800, using Software version 6.00.04)	<a href="#">FDA</a>	N.A.	News Release	2010/01/29	N.A.	N.A.