Health Canada Santé Canada

Mandatory Medical Device Problem Reporting Form for Industry

CANADA VIGILANCE - MEDICAL DEVICE PROBLEM REPORTING PROGRAM

If more space is required, please attach additional sheets
Fields required to be completed for updates/final reports are indicated by an *

A. REPORTER INFORMATION

1. i. Reporter Type

(○) Manufacturer (◉) Importer

In the case where the reporter is the importer:

ii. Did the importer report the incident to the manufacturer?

(◉) Yes (○) No

iii. Is the importer also submitting the report on behalf of the manufacturer?

(◉) Yes (○) No

2. Reporter Contact Information *

892796eedbbd2e1466bdd68388ce71f4

3. Reporter File No. *

CASE-2019-00101096

4. Health Canada File No. (if applicable) *

5. Type of Report *

(◉) Preliminary (○) Update (○) Final (○) Preliminary & Final

If "preliminary" only, anticipated date for the final report:

2020-03-27 (YYYY-MM-DD)

If "update/final", date the previous report was submitted to Health Canada:

(YYYY-MM-DD)

6. Date Submitted *

2022-03-02 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	CARDINAL HEALTH 200, LLC (CARRYING ON THE PATIENT RECOVERY BUSINESS FROM COVIDIEN LLC) 15 Hampshire Street Mansfield, MA, US, 02048	CARDINAL HEALTH CANADA INC. 1330 Meyerside Drive Mississauga, ON L5T 1C2
8. Health Canada assigned company identification number (if known):	133787	104924
9. Establishment License Number (if applicable):	N/A	203

B. INCIDENT INFORMATION

1. Classification of Incident *

i. (○) 10-Day (◉) 30-Day

ii. (◉) Canadian (○) Foreign

iii. (○) Investigational testing (○) Special Access Program (○) Radiation emitting device (if applicable)

2. Date of Incident

2019-12-12 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-12-17 (YYYY-MM-DD)

4. Patient Consequences

64c52c975613b7c9cba4be892611f5e4

5. Details of Incident

26af7bd0fa766f52bdbaf3e5e67a7999

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
MAGELLAN TUBERCULIN SAFETY SYRINGE PERMANENT NEEDL

2. Control/Lot/Serial No.
921759X

3. Expiration Date
(YYYY-MM-DD)

4. i. Device Classification
○ I ◉ II ○ III ○ IV

ii. Device License No.
85473

iii. Device Identification No
8881882712

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
8881882712

5. Software Version
N/A

6. Age of Device
N/A

7. How long was the device in use?
Device first issue date: 2013-02-07

8. Was the device labelled as sterile?
◉ Yes ○ No

9. Availability of device for evaluation
○ Destroyed ○ Returned to Manufacturer/Importer
◉ Neither (with explanation)

Syringe was filled with Heparine and disposed of.

D. COMPLAINANT INFORMATION

1. Complainant is a:
○ Consumer ◉ Health professional ○ Other

2. Name of Complainant
54f69d45d49414192b60aa157112866a

3. Name of Health Care Facility (if applicable)
989f767d147ec124494fb2e17c0812bc

4. Address
3d56c08d62d1febe5a8218da2f890f52

5. Telephone No. and/or E-mail Address
fee5766d72d9d0a4d0dcf7e9b87bc0c2

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E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline
2ca76d14ecc1cd8a679dffd6066b480c

2. Root Cause of Problem
95cec7fbf076d62538f183af61e2c82e

3. Corrective Actions taken as a result of the investigation
95cec7fbf076d62538f183af61e2c82e