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 *

fc0b18b00c98a4158a51a030f71c3e61

3. Reporter File No. *

INF-US-2019-001180 (283351)

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:

(YYYY-MM-DD)

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

2019-02-01 (YYYY-MM-DD)

6. Date Submitted *

2020-09-18 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	CareFusion Switzerland 317 Sarl A-One Business Centre Zone D'Activites Vers-La-Piece No 10 Rolle, Switzerland, 1180	Becton Dickinson Canada Inc., 2100 Derry Road, Suite 100, Mississauga, Ontario Canada L5N 0B3
8. Health Canada assigned company identification number (if known):	123422	101291
9. Establishment License Number (if applicable):	Not Applicable	204

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

(YYYY-MM-DD)

3. Reporter's Awareness Date

(YYYY-MM-DD)

4. Patient Consequences

60b725f10c9c85c70d97880dfe8191b3

5. Details of Incident

d41d8cd98f00b204e9800998ecf8427e

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
Alaris Syringe module set

2. Control/Lot/Serial No.

3. Expiration Date
(YYYY-MM-DD)

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

ii. Device License No.

iii. Device Identification No

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

5. Software Version

6. Age of Device

7. How long was the device in use?

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

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

D. COMPLAINANT INFORMATION

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

2. Name of Complainant
d41d8cd98f00b204e9800998ecf8427e

3. Name of Health Care Facility (if applicable)
d41d8cd98f00b204e9800998ecf8427e

4. Address
d41d8cd98f00b204e9800998ecf8427e

5. Telephone No. and/or E-mail Address
d41d8cd98f00b204e9800998ecf8427e

Privacy Notice Statement: For the purposes of the Canada Vigilance - Medical Device Problem Reporting Program, information related to the identity of the complainant and/or reporter will be protected as personal information under the *Privacy Act*, and under the *Access to Information Act* in the case of an access to information request. For details with regard to personal information collected under this program, visit the Personal Information Bank; Health Canada; Health Products and Food Branch; Branch Incident Reporting System; HC PPU 088 at: http://infosource.gc.ca/inst/1476/1476-fedemp00-eng.asp

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline
dfcbe10bce9f81ec8ece787b0361db1c

This section only applies for preliminary & final, and final reports

2. Root Cause of Problem
aa6d904976acaaff8c251913c70f5164

3. Corrective Actions taken as a result of the investigation
cd2ce79d8de944916cf0c465b633ca85