

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 *

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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 *

feccc214a655f645dd2a1a45e9fd8d5c

3. Reporter File No. *

002169190A

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:

2020-04-28

(YYYY-MM-DD)

6. Date Submitted *

2020-08-20

(YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address		
8. Health Canada assigned company identification number (if known):		
9. Establishment License Number (if applicable):		

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)

5. Details of Incident

2. Date of Incident

2020-02-02 (YYYY-MM-DD)

3. Reporter's Awareness Date

2020-07-22 (YYYY-MM-DD)

4. Patient Consequences

e61171666d4d253627ba818b28c8512f

C. MEDICAL DEVICE INFORMATION**1. Trade/Brand Name ***

Playtex Sport Multipack Tampon Unknown

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**

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3. Name of Health Care Facility (if applicable)

d41d8cd98f00b204e9800998ecf8427e

4. Address

d41d8cd98f00b204e9800998ecf8427e

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

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E. INVESTIGATION INFORMATION**1. Investigative Actions and Timeline**

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

2. Root Cause of Problem

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3. Corrective Actions taken as a result of the investigation

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