

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 *

Page 1 of 2

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 *

512e5dbcf0604ebf69c1a8f8194b14e4

3. Reporter File No. *

PR-1626761-1634780

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

NOT AVAILABLE

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:

2019-06-05

(YYYY-MM-DD)

6. Date Submitted *

2020-07-16

(YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	BAXTER HEALTHCARE SA Po Box 8010 Zurich, CH, 8010	BAXTER CORPORATION, 7125 MISSISSAUGA ROAD, MISSISSAUGA, ON, L5N 0C2
8. Health Canada assigned company identification number (if known):	129789	101173
9. Establishment License Number (if applicable):	N/A	191

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

d5aac35db096756d4ced8b95701c867e

2. Date of Incident

2019-02-12 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-03-11 (YYYY-MM-DD)

4. Patient Consequences

5b3d77cc6a3db5bf90de5e6d3833860e

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

EXACTA-MIX EVA CONTAINER

2. Control/Lot/Serial No.

60131932

3. Expiration Date

(YYYY-MM-DD)

4. i. Device Classification

I II III IV

ii. Device License No.

5557

iii. Device Identification No

740

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

H938740

5. Software Version

Not Applicable

6. Age of Device

Not Available

7. How long was the device in use?

UNKNOWN

8. Was the device labelled as sterile?

Yes No

9. Availability of device for evaluation

Destroyed Returned to Manufacturer/Importer
 Neither (with explanation)

Two samples were returned for evaluation.

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

This is being submitted as an update to the final mandatory

d4b0c1977727daad38f5a9bc6650c489

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

2. Root Cause of Problem

69d974ee6241be10a0a1e7ff7f5ebe2c

3. Corrective Actions taken as a result of the investigation

13d927ef4067567b08e383485c0fb480

D. COMPLAINANT INFORMATION**1. Complainant is a:**

Consumer Health professional Other

2. Name of Complainant

d6a4463eb2f9b913966de07b937cb541

3. Name of Health Care Facility (if applicable)

0b2398a17502c77b6ed621dbcd17eba9

4. Address

ac8a9b87a98367695477567532a69c20

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

c7a9ab20175e49d7f76d1fdb4a1acec8

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