

## 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 \*

512e5dbcf0604ebf69c1a8f8194b14e4

#### 3. Reporter File No. \*

PR-1626761-1634746

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

3feaa8979dfeab0c3867cce3e51d9977

#### 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.**

60066275

**3. Expiration Date**

2020-05-31

(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)

The sample has been returned to Baxter for evaluation.

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

This is being submitted as an update to the final mandatory

fabb5c605f214e52bbd6c301d7e913f2

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

**2. Root Cause of Problem**

69d974ee6241be10a0a1e7ff7f5ebe2c

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

13d927ef4067567b08e383485c0fb480

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ac8a9b87a98367695477567532a69c20

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

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