

## 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 \*

706571d1cf2e7b2a8e5acb18e05b3ab2

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

PR-1626761-1634758

#### 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

#### 2. Date of Incident

Unknown (YYYY-MM-DD)

#### 3. Reporter's Awareness Date

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

#### 4. Patient Consequences

a1f0e5c7f968895c91cfb249d8a8559d

5b3d77cc6a3db5bf90de5e6d3833860e

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

EXACTA-MIX EVA CONTAINER

**2. Control/Lot/Serial No.**

60132231

**3. Expiration Date**

2021-05-31

(YYYY-MM-DD)

**4. i. Device Classification**

I     II     III     IV

**ii. Device License No.**

5557

**iii. Device Identification No**

741

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

H938741

**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 was returned for evaluation.

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

This is being submitted as an update to the final mandatory

fe479309327d94b5cc84e1d2960ce7a5

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

**2. Root Cause of Problem**

eb3a65fea6dfd9358374c1fbc434d04e

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

13d927ef4067567b08e383485c0fb480

**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>

ac8a9b87a98367695477567532a69c20

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

c7a9ab20175e49d7f76d1fdb4a1acec8