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 *

J
je
P b322f2ef9cbc290f7213ddb7969362f7
F:

3. Reporter File No. *

MDPR-2019-00696-01

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:

2019-12-19 (YYYY-MM-DD)

6. Date Submitted *

2020-12-18 (YYYY-MM-DD)

		Importer
7. Name and Address	St. Jude Medical, CRMD 15900 Valley View Court Sylmar, CA 91342	Abbott Medical Canada, Co. 6975 Creditview Rd Unit #1 Mississauga, ON, Canada L5N 8E9
8. Health Canada assigned company identification number (if known):	107942	107941
9. Establishment License Number (if applicable):		19

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

2019-07-20

3. Reporter's Awareness Date

2019-11-29

4. Patient Consequences

T

903e89118b29a0082b72c6e270dd6fc2

5. Details of Incident

9fe7f6a297e5c8fed234f4cc8fa023f4

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
FORTIFY ASSURA VR

2. Control/Lot/Serial No.
5409297

3. Expiration Date
2016-07-31 (YYYY-MM-DD)

4. i. Device Classification
☐ I ☐ II ☐ III ☑ IV

ii. Device License No.
84623

iii. Device Identification No
573137

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
CD1359-40C

5. Software Version
N/A

6. Age of Device
2014-07-20

7. How long was the device in use?
1596 days

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
Ca0b82f869516b4db893a0de1cd60cfcb

3. Name of Health Care Facility (if applicable)
K44479b129ca9b9cb55c3ecf282e66410

4.
7
K
K1ca5b90dbb6cdc2302d698419f185c58

5.
6

92257930dfdc518e00098932a0cf6326

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

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

2. Root Cause of Problem

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a294c0e9ef3455e0643a1c7351e72bd8

3. Corrective Actions taken as a result of the investigation

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