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*

3. Reporter File No.*

18825114

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

5. Type of Report*

○ Preliminary ● Update ○ Final ○ Preliminary and Final

If "preliminary" only, anticipated date for the final report:

If "update/final", date the previous report was submitted to Health Canada:

2020/01/24

2f0a7996b967f1515f8ac52d3b7f4518

te Submitted *

/07/23

	Manufacturer	Importer
7. Name and Address	Abbott Diabetes Care LTD. Range Road Witney, OX, GB OX290YL	Abbott Laboratories LTD 7115 Millcreek DR Mississauga, Ont L5N
8. Health Canada assigned company identification number (if known):	134918	
9. Establishment License Number (if applicable):		208

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

2019/11/19

3. Reporter's Awareness Date

2019/11/20

4. Patient Consequences

5. Details of Incident

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cb414391e2a1b4b1d5f68a8ad5495c47

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
Freestyle Libre

2. Control/Lot/Serial No
3MH000PT1E4

3. Expiration Date
2019/11/20

4. i. Device Classification

○ I ○ II ◉ III ○ IV

ii. Device License No.
99351

iii. Device Identification No
799431

iv. Manufacturer's Medical Device Identifier(catalogue/model no.)
71534-01

5. Software Version
NA

6. Age of Device
Unknown

7. How long was the device in use?
7 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

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d41d8cd98f00b204e9800998ecf8427e

73b6ce9500f783c59b1b739f2fb33ca7

d41d8cd98f00b204e9800998ecf8427e

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E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

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This section only applies for preliminary and 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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Joey Larrowe Alameda 25Jun2020