Protected A
(When completed)

Medical Device Recall Reporting Form - Final

Purpose: To capture the information manufacturers and importers are required to report to Health Canada as soon as possible after the completion of a recall, as per S. 65 of the *Medical Devices Regulations*. Refer to the Guide to Recall of Medical Devices for more information. The personal information you may provide to Health Canada is governed in accordance with the *Privacy Act* and is collected to administer the Medical Device Compliance and Enforcement program authorized under the *Food and Drugs Act.* This personal information collection is described in Info Source, available online at infosource.gc.ca. Refer to the personal information bank HC PPU 405. For more information about our privacy practices, please contact the Privacy Management Division - Director at 613-355-1458 or privacy-vie.privee@hc-sc.gc.ca. For any other questions, please contact the appropriate regional office, as identified at the end of this form. Use of this form is optional. All information collected on this form will be treated as confidential business information.

Submitter Type: Importer

If an importer, are you reporting on behalf of the manufacturer? No

Health Canada recall #: 206062

Company Recall Reference Number (if applicable): CAR21.348-164848

65 (a) the results of the recall (Include information on the effectiveness of the recall action, confirmation that all accounts have received the recall notice and that any on-site corrections have been completed. Provide a reconciliation of all product affected by the recall, where appropriate, and a rationale for any discrepancies.) For more detail on the information required by Section 65, see the Guide to Recall of Medical Devices located on the Health Canada website at: Guide to Recall of Medical Devices [Health Canada] *Note: Add additional information as attachments*

A total of 34 customers were contacted and 10 responded, 1 is no longer in business and all others were non responsive. Each customer was contacted at least twice. The top 10 customers having the largest volume of units in the field were also contacted by Levitt Safety Customer Service Representatives directly. In total, 653 out of 18 884 thermometers were removed from service, and a total of 4 809 were accounted for. (Reference attached spreadsheet entitled Customer Response Data for HC Recall 206062.) Of the customers that responded, the majority of them indicated that the affected units were widely distributed to their employees and their families in the early stages of the COVID-19 pandemic and since there was a low risk of the device failure the company decided not to pursue remedial actions. This is likely why such a large part of the customer group did not respond to our communications. In addition, Levitt Safety has posted the original recall notice in the Product Notices and Recalls section of our corporate website to enable access for our customers and the public.

Date the recall was completed in Canada:	yyyy-mm-dd	2022-11-30

65 (b) the action taken to prevent a recurrence of the problem (provide a description of all actions taken to prevent a recurrence of the problem) *Note: Add additional information as attachments*
There are no plans for the vendor to apply for a MDL for the product, therefore this vendor has been removed from our approved vendor list and the product is no longer offered for sale; it is marked obsolete within the internal customer service software portal and is no longer accessible on our e-commerce website The product has been effectively deleted and is no longer imported or sold by Levitt Safety.

In the case of class II, III and IV devices, actions have been evaluated against S. 34 of the MDR to determine if a device licence amendment is required (click on box to confirm)**:** ☑

Health Canada Contacts for Reporting Medical Devices Recalls

Notification of recall is submitted to the appropriate Region. Companies that do not know under which Region they fall, can contact the Regulatory Operations and Region Branch at: 1-800-267-9675

Location of Recalling Firm	Recall Reporting Address
Canada: New Brunswick, Newfoundland and Labrador, Nova Scotia, Prince Edward Island **USA:** Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, Rhode Island, Vermont **World:** Middle East (Bahrain, Cyprus, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Syria, Turkey, United Arab Emirates, West Bank and Gaza Strip, Yemen)	**Atlantic Region:** Medical Devices Compliance Program, Suite 1625, 16th Floor, 1505 Barrington Street, Halifax, Nova Scotia B3J 3Y6 Phone: 902-426-2160 Fax: 902-426-6676 Email: ATL-MED@HC-SC.GC.CA
Canada: Quebec **USA:** District of Columbia, Florida, Georgia, New York, North Carolina, Pennsylvania, South Carolina, Virginia, West Virginia **World:** All islands in the Caribbean, Central America (Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama), Scandinavia and Baltic States (Denmark, Estonia, Finland, Latvia, Lithuania, Norway, Sweden), Central Europe (Austria, Belgium, France, Germany, Liechtenstein, Luxembourg, Netherlands, Switzerland)	**Quebec Region:** Medical Devices Compliance Program, 1001 Rue St-Laurent Ouest Longueuil, Quebec, J4K 1C7 Phone: 450-646-1353 Fax: 450-928-4105 Email: QUE-MED@HC-SC.GC.CA

Canada: Ontario **USA:** Alabama, Illinois, Indiana, Kentucky, Michigan, Mississippi, Ohio, Tennessee, Wisconsin **World:** Northern Europe (Iceland, Ireland, England, Scotland, Wales, Northern Ireland), Eastern Europe (Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Serbia, Slovak Republic, Slovenia), Southern Europe (Greece, Holy See, Italy, Malta, Monaco, Portugal, San Marino, Spain), all countries in South America	**Ontario Region:** Medical Devices Compliance Program, 2301 Midland Ave. Toronto, Ontario, M1P 4R7 Phone: 416-973-1600 Fax: 416-954-4581 Email: ONT-MED@HC-SC.GC.CA
Canada: Manitoba, Saskatchewan **USA:** Arkansas, Iowa, Kansas, Louisiana, Minnesota, Missouri, Nebraska, North Dakota, Oklahoma, South Dakota, Texas **World:** All countries in Africa, Mexico	**Manitoba-Saskatchewan Region:** Medical Devices Compliance Program, 100 - 391 York Avenue Winnipeg, MB R3C 4W1 Phone: 204-594-8061 Fax: 204-594-8153 Email: MS-MED@HC-SC.GC.CA
Canada: Alberta, Northwest Territories, Nunavut **USA:** Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming **World**: Australia, New Zealand, All islands in the South Pacific	**Alberta Region:** Medical Devices Compliance Program, Suite 730, 9700 Jasper Avenue, Edmonton, Alberta, T5J 4C3 Phone: 780-495-6815 Fax: 780-495-2624 Email: AB-MED@HC-SC.GC.CA
Canada: British Columbia, Yukon **USA:** Alaska, California, Hawaii , Oregon , Washington **World:** All countries in Asia	**British Columbia Region:** Medical Devices Compliance Program, 400 - 4595 Canada Way Burnaby, British Columbia, V5G 1J9 Phone: 604-666-3350 Fax: 604-666-3149 Email: WOC-MED@HC-SC.GC.CA