ORDER OF AN EXECUTIVE OFFICER

To: Leah Verstraete
"the Owner"

RE: Those premises located in Calgary, Alberta and municipally described as:
Smile Blanc located at 620 10 Ave SW #130, Calgary, AB T2R 1C3

WHEREAS I, an **Executive Officer** of **Alberta Health Services**, have inspected the above noted premises pursuant to the provisions of the Public Health Act, RSA 2000, c. P-37, as amended;

AND WHEREAS such inspection disclosed that the following conditions exist in and about the above noted premises which are or may become injurious or dangerous to the public health or which might hinder in any manner the prevention or suppression of disease, namely:

a. Used medical devices were not being transported to the medical device reprocessing area in a labeled and sealed container.
b. Only gloves were being donned when reprocessing medical devices.
c. The performance of the Hydrim G4 automated washer was not being tested each day that it was in use. The test indicators that were available expired in 2023 and only 7 out of the 32 indicators that came in the original packaging had been used.
d. Cleaned cassettes were being wrapped in the dirty section of the medical device reprocessing area.
e. The size of the non-woven wrap was not adequate to properly wrap the cassette.
f. Records confirming biological monitoring of the sterilizer were not available.
g. Internal chemical indicators were not used with the peel pouched packages.
h. The Type 4 chemical indicators that were available expired in 2022.
i. Peel pouches were loaded plastic side down in the Midmark M9 sterilizer.
j. Peel pouches and wrapped cassette were sterilized together using the Pack cycle of the Midmark M9 sterilizer.
k. The medical device reprocessing personnel were not monitoring the physical parameters of the sterilizer cycle prior to the load being released.
l. Records of installation and operational qualification of the Midmark M9 sterilizer were not available.
m. Written policies and procedures for medical device reprocessing were not available.
n. Three unlabeled trays of unpackaged medical devices were placed on the counter in the medical device reprocessing area. Staff were not sure if the medical devices had been cleaned or not.
o. The facility owner has a dog that follows her around the clinic. The dog is free to roam around the facility, and there is no door to the medical reprocessing area to prevent the dog from entering.
p. Based on the number of deficiencies found, it is clear that the medical device reprocessing personnels were neither appropriately educated nor trained for the reprocessing duties/tasks they were performing.

AND WHEREAS such inspection disclosed that the following breaches of the Public Health Act and the Nuisance and General Sanitation Regulation, Alberta Regulation 243/2003 exist in and about the above noted premises, namely:

a. Used medical devices were not being transported to the medical device reprocessing area in a labeled and sealed container. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
b. Only gloves were being donned when reprocessing medical devices. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
c. The performance of the Hydrim G4 automated washer was not being tested each day that it was in use. The test indicators that were available expired in 2023 and only 7 out of the 32 indicators that came in the original packaging had been used. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
d. Cleaned cassettes were being wrapped in the dirty section of the medical device reprocessing area. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
e. The size of the non-woven wrap was not adequate to properly wrap the cassette. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
f. Records confirming biological monitoring of the sterilizer were not available. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
g. Internal chemical indicators were not used with the peel pouched packages. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
h. The Type 4 chemical indicators that were available expired in 2022. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
i. Peel pouches were loaded plastic side down in the Midmark M9 sterilizer. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
j. Peel pouches and wrapped cassette were sterilized together using the Pack cycle of the Midmark M9 sterilizer. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
k. The medical device reprocessing personnel were not monitoring the physical parameters of the sterilizer cycle prior to the load being released. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.

l. Records of installation and operational qualification of the Midmark M9 sterilizer were not available. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
m. Written policies and procedures for medical device reprocessing were not available.
n. Three unlabeled trays of unpackaged medical devices were placed on the counter in the medical device reprocessing area. Staff were not sure if the medical devices had been cleaned or not. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
o. The facility owner has a dog that follows her around the clinic. The dog is free to roam around the facility, and there is no door to the medical reprocessing area to prevent the dog from entering. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.
p. Based on the number of deficiencies found, it is clear that the medical device reprocessing personnels were neither appropriately educated nor trained for the reprocessing duties/tasks they were performing. This is a contravention of section 2(1) of the Nuisance Regulation which states that: A practice or condition at this facility is creating a nuisance. No person shall create, commit or maintain a nuisance.

NOW THEREFORE, I hereby **ORDER** and **DIRECT**:

1. That the Owner immediately undertake and diligently pursue the completion of the following work in and about the above noted premises, namely:

    a. Cease medical device reprocessing immediately. Should the facility wish to resume medical device reprocessing, corrective actions ‘b through r’ below must be adhered to..
    b. All medical device reprocessing personnel shall receive training in medical device reprocessing. This training must be recognized by the Environmental Public Health Department. Provide records of the completed training to an Executive Officer of Alberta Health Services.
    c. Obtain and use all necessary personal protective equipment when reprocessing medical devices, including gowns, protective eyewear, and gloves.
    d. Provide a container with a lid to transport dirty medical devices to the medical device reprocessing area. Properly label the container to identify its contents. The label must be able to withstand repeated cleaning and disinfection and must be replaced when it becomes too worn.
    e. Discard all expired test indicators. Obtain new test indicators to test the Hydrim G4 automated washer each day that it is in use and document the results.
    f. Refrain from using expired test indicators.
    g. Clearly identify the one-way workflow in the medical device reprocessing area within the facility-specific written MDR policies and procedures.
    h. Create and put in place a system to clearly identify non-reprocessed devices from ones that have been reprocessed to prevent use of contaminated devices on clients.
    i. Obtain appropriate non-woven wraps such that cassettes can be properly and fully wrapped in accordance with the guidelines of the Canadian Standards Association on medical device reprocessing in all health care settings.

j. Provide evidence that biological monitoring has been conducted (i.e. invoices of biological indicators purchased since opening of business). Results of biological indicators must be monitored and documented.
k. Obtain new chemical indicators and place one in each peel pouched package to be sterilized. Do not use expired chemical indicators.
l. Monitor and document results of internal chemical indicators.
m. Review the manual of the Midmark M9 and ensure the correct cycle is used for the packages being sterilized.
n. Maintain a log with each sterilization cycle recorded on-site.
o. Upload the data logger results after each sterilization cycle and verify that all cycle parameters are met before releasing the load.
p. Provide records of installation and operation qualifications of the Midmark M9 sterilizer to an Executive Officer of Alberta Health Services.
q. Provide a copy of the written policies and procedures on medical device reprocessing to an Executive Officer with Alberta Health Services.
r. Construct a door or other suitable method to restrict animal access to the medical device reprocessing area. Alternatively, refrain from bringing animals to the facility.

2. The work referred to in paragraph 1b to 1r shall be completed by May 15, 2024.

The above conditions were noted at the time of inspection and may not necessarily reflect all deficiencies. You are advised that further work may be required to ensure full compliance with the Public Health Act and regulations, or to prevent a public health nuisance.

DATED at Calgary, Alberta, April 24, 2024.

Confirmation of a verbal order issued to Leah Verstraete on April 22, 2024.

Executive Officer
Alberta Health Services

You have the right to appeal

A person who a) is directly affected by a decision of a Regional Health Authority, and
b) feels himself aggrieved by the decision

may appeal the decision by submitting a Notice of Appeal form within ten (10) days after receiving the order to:

Public Health Appeal Board
c/o Central Reception
Main Floor, ATB Place North Tower
10025 Jasper Avenue NW
Edmonton, Alberta, T5J 1S6
Phone: 780-222-5186

Fax: 780-422-0914
Email: HealthAppealBoard@gov.ab.ca
Website: https://www.alberta.ca/public-health-appeal-board.aspx

A Notice of Appeal form may be obtained by contacting the Public Health Appeal Board or visiting their website.

Health Legislation, Regulations and Standards

Electronic versions of the Public Health Act and Regulations are available at the Alberta King's Printer Bookstore 10611 - 98 Avenue, Main Floor, Park Plaza, Edmonton, Alberta, T5K 2P7 or https://www.alberta.ca/alberta-kings-printer.aspx.

Health Legislation and regulations are available for purchase. Please contact Alberta King's Printer Bookstore 10611 - 98 Avenue, Main Floor, Park Plaza, Edmonton, Alberta, T5K 2P7 or https://www.alberta.ca/alberta-kings-printer.aspx.

Copies of standards are available by visiting: https://www.alberta.ca/health-standards-and-guidelines.aspx

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