U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

March 10, 2020

Bob Richard
President
Hazmat Safety Consulting
5724 North Pulaski Road
Chicago, IL 60646

Reference No. 19-0036

Dear Mr. Richard:

This letter is in response to your March 15, 2019, email requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to a glucose monitoring health care product. Specifically, you describe the device and its handling, as follows, and ask whether it should be transported as a Division 6.2, medical waste or used healthcare product:

- The device has a very small sharp that is imbedded in a hard-plastic casing and is not accessible;
- The sharp only penetrates the outer level of skin when the spring-loaded applicator is pressed against the skin, and a patch is applied;
- Following use, the device and patch are sent for recycling to a designated collection site;
- A return kit is provided to the user and they are instructed to rinse the device prior to placing it in the packaging and shipping for recycling.

In accordance with § 173.22, it is the shipper's responsibility to properly classify a hazardous material and this Office does not normally perform this function. That said, in the absence of explicit instruction from the manufacturer to fully inform the customer on pathogen concerns and how to disinfect the device, there are three potential shipping scenarios for the user returning the kit:

1. If the person returning the kit determines that the device is not known or reasonably expected to contain a pathogen, either because the user has not exposed the device to a pathogen or has disinfected it, then it does not meet the definition of a Division 6.2 infectious substance and does not need to be shipped as a hazardous material. Note, the instruction to rinse the device may not be sufficient to remove a pathogen.

If the person returning the kit has knowledge or a reasonable expectation that the device contains a pathogen, the device may not be offered for transportation without being appropriately classified, described, and packaged as a Division 6.2 infectious substance.

2. If the person returning the kit determines that the device is known or reasonably expected to contain a pathogen that meets the definition of a Category B infectious substance, it must be shipped as "UN3291, Regulated medical waste, n.o.s., 6.2, II."
3. If the person returning the kit determines that the device is known or reasonably expected to contain a pathogen that meets the definition of a Category A infectious substance, it must be shipped as "UN2814, Infectious substances, affecting humans, 6.2."

The accompanying brochure, "Transporting Infectious Substances Safely," may assist your client in providing instruction to the customer in making the determination if the return kit must be shipped as containing a hazardous material. Customers may also wish to seek assistance on classification and packaging requirements from the common carrier that they are using to ship the return kit.

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,

Dirk Der Kinderen
Chief, Standards Development Branch
Standards and Rulemaking Division

Geller

19-0236

Dodd, Alice (PHMSA)

From: Foster, Glenn (PHMSA)
Sent: Wednesday, March 27, 2019 3:18 PM
To: Dodd, Alice (PHMSA); January, Ikeya CTR (PHMSA)
Cc: DerKinderen, Dirk (PHMSA); Foster, Glenn (PHMSA); Kelley, Shane (PHMSA); Nickels, Matthew (PHMSA)
Subject: Glucose monitor

Alice / Ikeya

Please have the email from Bob Richard checked in as a request for an Interp and assign to a Specialist.

Thanks,
Glenn

From: Kelley, Shane (PHMSA)
Sent: Wednesday, March 27, 2019 10:20 AM
To: Foster, Glenn (PHMSA) <Glenn.Foster@dot.gov>
Subject: FW: Glucose monitor

Can you call Bob today and see if you think we should accept a meeting request? I am ok either way, just want to close the loop!

Thanks

From: Edmonson, Eileen (PHMSA)
Sent: Friday, March 15, 2019 2:54 PM
To: Bob Richard <brichard@hazmatsafety.com>
Cc: Kelley, Shane (PHMSA) <shane.kelley@dot.gov>; Foster, Glenn (PHMSA) <Glenn.Foster@dot.gov>; Mike Pagel <mpagel@hazmatsafety.com>; Pfund, Duane (PHMSA) <Duane.Pfund@dot.gov>
Subject: RE: Glucose monitor

Hi Bob,

Hope all is going well.

I've forwarded your request for a meeting to discuss the glucose monitor described below to PHH-10 and -13 leadership for consideration.

We will get back to you soon.

Sincerely,

Eileen Edmonson
Transportation Regulations Specialist
U.S. Department of Transportation/PHMSA
(w) 202-366-4481
(f) 202-366-7041
(email) eileen.edmonson@dot.gov

(Hazmat Info Center) 800-467-4922
(website) https://www.phmsa.dot.gov/

From: Bob Richard <brichard@hazmatsafety.com>
Sent: Friday, March 15, 2019 1:41 PM
To: Edmonson, Eileen (PHMSA) <eileen.edmonson@dot.gov>
Cc: Kelley, Shane (PHMSA) <shane.kelley@dot.gov>; Foster, Glenn (PHMSA) <Glenn.Foster@dot.gov>; Mike Pagel <mpagel@hazmatsafety.com>
Subject: Glucose monitor

Eileen,

My client has a health care product that is used for glucose monitoring. Because of FDA approval requirements once the product is used the patient cannot simply dispose of it in regular municipal waste streams even though the likelihood that it contains a pathogen is extremely remote. The device has a very small sharp that is not accessible in transport or to the user because it is imbedded in a hard plastic casing and is retracted to prevent inadvertent exposure. The skin piercing mechanism is imbedded in a hard robust casing and not accessible. The sharp only penetrates the outer level of skin when the spring loaded applicator is pressed against the skin. The device applies a patch to the pierced skin that can monitor glucose levels for up to two weeks. This video shows how the product works: https://www.freestylelibre.us/support/overview.html click apply the sensor.

Once the device is used and the patch is removed the patient is instructed to send it for recycling to a designated collection site. The patient is provided with a return kit and instructed to rinse the product prior to placing it in the package and shipping it further eliminating any chance that it contains a pathogen. I believe that on the basis that the device is unlikely to contain a pathogen it should not be considered a Division 6.2 substance. I don't believe it should be required to be transported as a medical waste or used healthcare product. I could apply for a written interpretation but I think it would make more sense to demonstrate how the product is used, packaged and transported either by coming in for a face to face meeting or scheduling a WebEx prior to submitting a request for an interpretation. I would like to schedule a time to provide a presentation where we can provide a demonstration of the product and the shipping process. The client is a company that has a strong safety culture and compliance program. The product does not generate a significant profit for the company. They distribute as an altruistic initiative to promote public health and in the interest of their customers. If they would need to ship the used kits back as a regulated commodity they would not likely to distribute the product which would be unfortunate for potential users.

Best Regards,

Bob Richard
President, Hazmat Safety Consulting
Phone: 773-540-0837
Email: brichard@hazmatsafety.com
www.hazmatsafety.com

From: Edmonson, Eileen (PHMSA) <eileen.edmonson@dot.gov>
Sent: Friday, March 1, 2019 2:22 PM
To: Bob Richard <brichard@hazmatsafety.com>
Cc: Kelley, Shane (PHMSA) <shane.kelley@dot.gov>; Foster, Glenn (PHMSA) <Glenn.Foster@dot.gov>
Subject: RE: Have time for a quick question today?

Hello Bob,

I found two letters of clarification, one linked and the other attached as a PDF, PHMSA issued in the past on "Used health care products." I believe they address your question. However, these letters are older, so some of the section references may have changed.

> 4/2/2012 Ref No 12-0028
> https://www.phmsa.dot.gov/regulations/title49/interp/12-0028

If you need additional information, please let us know by "replying" all to this message.

Thanks,

Eileen Edmonson
Transportation Regulations Specialist
U.S. Department of Transportation/PHMSA
(w) 202-366-4481
(f) 202-366-7041
(email) eileen.edmonson@dot.gov
(Hazmat Info Center) 800-467-4922
(website) https://www.phmsa.dot.gov/

From: Bob Richard <brichard@hazmatsafety.com>
Sent: Tuesday, February 26, 2019 12:37 PM
To: Edmonson, Eileen (PHMSA) <eileen.edmonson@dot.gov>
Cc: Kelley, Shane (PHMSA) <shane.kelley@dot.gov>
Subject: FW: Have time for a quick question today?

Eileen,

I am hoping you can assist me. I have a client that needs to have their glucose monitors returned from patients. The client will provide the patients with return kits. The devices will be sent to a facility for recycling. I am trying to determine if they can ship the devices as "used health care products" or as "regulated medical devices". Please note the information below.

https://www.freestylelibre.us/system-overview/freestyle-14-day.html

Discover the FreeStyle Libre 14 day system

Get ready to make fingersticks a thing of the past![*]

What is it?

The FreeStyle Libre 14 day system is a **continuous glucose monitoring system** consisting of a **handheld reader** and a sensor worn on the back of the upper arm

How does it work?

The sensor uses a thin, flexible filament inserted just under the skin to **measure glucose every minute**

How do you use it?

Use the handheld reader to scan the sensor with a **painless,[4] one-second scan** to replace fingersticks [*]

The middle photo shows a side view of the sensor. The sensor is 26 mm in diameter, and "thin, flexible filament" protrudes 5 mm from the base of the sensor.

A video showing how the sensor is applied is included here:
https://www.freestylelibre.us/support/overview.html

Prior to insertion in the skin, the thin filament is nested in annular-shaped stainless steel sharp. The fully extended, the stainless sharp injects into the skin ~ 7mm, and then immediately retracts into the applicator unit, leaving the thin filament in the skin. Part of the FDA filing required Abbott proving that the stainless steel sharp reliably retracts so that the sharp is no longer exposed.

Regulated medical waste or clinical waste or (bio) medical waste means a waste or reusable material derived from the medical treatment of an animal or human, which includes diagnosis and immunization, or from biomedical research, which includes the production and testing of biological products. Regulated medical waste or clinical waste or (bio) medical waste containing a Category A infectious substance must be classed as an infectious substance, and assigned to UN2814 or UN2900, as appropriate.

Used health care product means a medical, diagnostic, or research device or piece of equipment, or a personal care product used by consumers, medical professionals, or pharmaceutical providers that does not meet the definition of a patient specimen, biological product, or regulated medical waste, is contaminated with potentially infectious body fluids or materials, and is not decontaminated or disinfected to remove or mitigate the infectious hazard prior to transportation.

Exceptions

(12) Laundry and **medical equipment and used health care products**, as follows:

(i) Laundry or medical equipment conforming to the regulations of the Occupational Safety and Health Administration of the Department of Labor in **29 CFR 1910.1030**. This exception includes medical equipment intended for use, cleaning, or refurbishment, such as reusable surgical equipment, or equipment used for testing where the components within which the equipment is contained essentially function as packaging. **This exception does not apply to medical equipment being transported for disposal.**

shipping for recycling not disposal.

(ii) Used health care products not conforming to the requirements in 29 CFR 1910.1030 and being returned to the manufacturer or the manufacturer's designee are excepted from the requirements of this subchapter when offered for transportation or transported in accordance with this paragraph (b)(12). For purposes of this paragraph, a health care product is used when it has been removed from its original packaging. Used health care products contaminated with or suspected of contamination with a Category A infectious substance may not be transported under the provisions of this paragraph.

(A) Each used health care product must be drained of free liquid to the extent practicable and placed in a watertight primary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. For a used health care product capable of cutting or penetrating skin or packaging material, the primary container must be capable of retaining the product without puncture of the packaging under normal conditions of transport. Each primary container must be marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030(g)(1)(i).

(B) Each primary container must be placed inside a watertight secondary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. The secondary container must be marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030(g)(1)(i).

(C) The secondary container must be placed inside an outer packaging with sufficient cushioning material to prevent movement between the secondary container and the outer packaging. An itemized list of the contents of the primary container and information concerning possible contamination with a Division 6.2 material, including its possible location on the product, must be placed between the secondary container and the outside packaging.

(D) Each person who offers or transports a used health care product under the provisions of this paragraph must know about the requirements of this paragraph.

Best Regards,

Bob Richard
President, Hazmat Safety Consulting
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Email: brichard@hazmatsafety.com
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