1. INTRODUCTION

The Sharps Medical Waste Services' (MWS) Single-Use Device (SUD) Program includes the collection and transportation of single-use medical devices through the TakeAway Systems. These devices are sent to SERI-certified vendors that adhere to the Responsible Recycling (R2) Standard Version 3 (v3). The program evaluates the single-use medical devices for potential reuse and recycling, with landfill disposal as a final option if necessary. It is designed to help reduce the impact that placing these devices in the trash can have on our environment, therefore, furthering healthcare organizations' sustainability goals. In addition, SUD Programs provides an alternative to the traditional reprocessing of single-use medical devices, which improves patient safety and outcomes by eliminating infections or injuries that could be caused by reprocessed single-use devices.

The Sharps MWS TakeAway Systems is available in the following configuration:

- One 12-Gallon Container
- Two 7.5-Gallon Containers

2. DESIGN REQUIREMENTS

The TakeAway Systems includes everything needed to collect, package, and ship devices prepaid for reclamation processing. The specially designated packaging can be used in many different clinical settings. When the collection containers are received at our processing facility, their contents are decontaminated and processed using approved protocols. The TakeAway Systems has been designed to fully comply with the U.S. Department of Transportation Used Health Care Products ("UHCP") exemption cited in 49 CFR 173.134 (a) (8) and 49 CFR 173.134 (b) (12) (ii).

See table below for additional regulatory requirements:

(A)	Each used healthcare 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 healthcare 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 UHCP under the provisions of this paragraph must know about the requirements of this paragraph.

3. PACKAGING

Each TakeAway Systems includes all components needed to properly and safely collect and ship devices for processing. The systems have undergone strict testing to assure adherence to U.S. Department of Transportation UHCP regulations (as shown above) and consists of:

- Polypropylene collection containers with the OSHA- compliant international "BIOHAZARD" label and absorbent material;
- Individual polypropylene collection container is placed inside a durable, watertight, 4-mil poly bag secured with a zip tie. The bag is marked with the "BIOHAZARD" label and is secured with a zip tie. This combination packaging is considered the watertight primary container as shown in (A) in the table above;
- The individually bagged primary containers are then placed in a secondary durable, watertight, 4-mil poly bag. This bag is marked with the "BIOHAZARD" label and secured with a zip tie. This secondary bag is considered the secondary watertight container as shown in (B) in the table above.
- The bagged containers are then placed in a sturdy and rigid outer packaging with sufficient cushioning material to prevent movement between the secondary container and the outer packaging;
- The System includes an itemized list of the contents of the primary container and information concerning possible contamination with a Division 6.2 material;
- The outer packaging includes a pre-attached UPS return shipping label (return freight is prepaid);
- Finally, the System includes a detailed pictorial Instruction for Use document, which is used to train individuals on the use of the System.

4. PACKAGING TESTING

The TakeAway Systems are tested to ensure that each system, packaging, and contents meet all requirements to be transported safely via common carrier. The complete TakeAway Systems successfully passes the Drop Test in CFR 49 § 178.603 and 178.606 Stacking Test for used healthcare products.

5. SHIPPING METHOD (Returned for Processing)

Sharps Medical Waste Services has a contract with United Parcel Service ("UPS") for the purpose of transporting TakeAway Systems via UPS ground.

6. SINGLE-USE DEVICE (SUD) PROGRAM

When the TakeAway Systems are received at our facility, the collection containers are removed, inspected, and weighed and the serial numbers are scanned. The contents of the collection containers are sorted using all appropriate safety controls as outlined by OSHA and CDC. Devices are appropriately disinfected or sterilized via industrial autoclave, based on device materials, in compliance with all established company protocol and best practices, as well as federal, state, and local regulations. The vast majority of the devices that will be processed by Sharps MWS are composed of plastics, aluminum, stainless steel, and titanium and some may also contain batteries and electronic components, such as circuit boards. After sorting and appropriate decontamination, devices are disassembled down to their core components based on material type and waste stream.

Plastics, batteries, stainless steel, electronics, aluminum, titanium, and copper, are recovered and transported to SERI-certified R2v3 partners for potential reuse and recycling, or landfill disposal as a final option if necessary.

7. CERTIFICATION

Once the devices have been processed for transportation to our SERI-certified R2v3 partners, processing data will be entered into the Sharps' MWS web-based tracking and reporting system, SharpsTracer. A Certificate will be made available for download.

8. RECORDKEEPING

As part of Sharps MWS' facility operations, records are maintained and kept current for the life of the facility and available for regulatory inspection at short notice. The operating records are a collection of relevant facility records, which may be an electronic and/or hard copy, demonstrating compliance with all applicable facility protocols and regulatory requirements. Records include, at a minimum:

- Copies of permits
- Dates of treatment
- Amount of materials treated
- Methods of treatment

9. ATTACHMENTS

- Instructions for Use
- Itemized Contents List