

**ULTIMED**  
INCORPORATED



## UltiMed Sharps Stewardship Plan

**Submitted by**

UltiMed, Inc.  
350 Highway 7  
Excelsior, MN 55331

**Submitted to**

California Department of Resources  
Recycling and Recovery (CalRecycle)  
1001 I Street  
Sacramento, CA 95812-4025

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## Perjury Statement

As required by CCR 18973(e), I hereby declare, under penalty of perjury, that the information provided in this document is true and correct, to the best of my knowledge.

Additionally, as required by CCR 18973.3(d)(2), I hereby certify that, at the time of submission to the Department, this stewardship plan, including all aspects of the plan related to the handling, transportation, and disposal of home-generated sharps waste, is in compliance with all applicable local, state, and federal laws and regulations.

A handwritten signature in black ink, appearing to be 'JE' with a long, sweeping horizontal stroke extending to the right.

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# Acknowledgements

UltiMed, Inc. wishes to thank the following entities and organizations, and their constituents and employees for their contributions, feedback, and assistance during the development of the UltiMed, Inc. (UMI) stewardship plan.



## **California Department of Resources Recycling and Recovery (CalRecycle)**

- Irina Kaminer, Attorney
- Jason Smyth, Senior Environmental Scientist, Supervisor
- Cynthia Dunn, Environmental Program Manager I, Supervisor
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- Marile Colindres, Associate Governmental Program Analyst
  - Clark Williams, Environmental Program Manager II
  - Mary Curry, Environmental Scientist
  - Becky Haworth, Environmental Scientist
- Eric Yee, Senior Environmental Scientist, Supervisor
  - Morgan Buchan, Environmental Scientist



## **PureWay, Inc. and PureWay Compliance, Inc.**

- Omar Al-Midani, Chief Executive Officer
- Richard Hadley, Chief Information Officer
- Jeffery Miglicco, Sr. Vice President, Sales and Marketing



## **California Product Stewardship Council**

- Kristina Miller, Chair
- Manuel Medrano, Vice Chair
- Tedd Ward, Treasurer
- Colleen Foster, Secretary
- Justin Lehrer, Senior Management Analyst StopWaste
- Christine Wolfe, Government Relations Manager
  - Steve Rodowick, Recycling Coordinator
  - Alexa Kielty, Zero Waste Specialist
- Wes Nelson, Sales & Marketing Manager
  - Amy Hammes, Recycling Specialist
- Derek Crutchfield, Recycling Coordinator
- Chris Sheppard, Senior Civil Engineer

## Plan Submittal Executive Summary

California Department of Resources Recycling and Recovery (CalRecycle) is missioned to solve complex issues surrounding the safe and secure management and disposal of sharps waste in the State of California. Not only does the State aim to solve inherent issues with medical wastes, it strives to perform mission endeavors at a high standard using effective and advanced means that build on an environmentally sound infrastructure. Vendors and manufacturers working in step with the State's mission must also meet the requirements by offering solutions that dovetail with current and in place requirements.

UltiMed, Inc. is an established manufacturer of injection devices for the human and veterinary diabetes markets and medical/surgical supply market. In addition to being a manufacturer for over 30 years, the company is a longtime proponent of safe sharps disposal. Beginning in 2002, we introduced the first and only *dispense & dispose* solution, combining the distribution of sharps with an FDA-cleared disposal container. Since launching of the first all-in-one system, the company has continued to evolve as an industry leader in safe sharps disposal. UltiMed recognized early on that there was an unmet challenge with the disposal of sharps that are used for in-home injections.

The organization and industry have progressed through education and legislation, and UltiMed continues to educate its customers on the benefits it offers as the market leader in providing sharps lifecycle management solutions.

More recently, increased legislative initiatives that support the company's long-standing leadership in sharps lifecycle management have been enacted. These recent changes prompted UltiMed to create a single, fully compliant product offering that is comprehensive and yet a simple solution. Our stewardship products comply with legislative directives, and more specifically, California Senate Bill 212 (SB-212).

As required by SB-212, we have submitted our stewardship plan and developed a fully compliant all-in-one solution that complies with every aspect of our responsibilities required by the new California law. Our product provides a sharps waste container and mail-back materials with all sharps dispensed in the State of California at no additional cost to the ultimate user. Our solution is not only effective but economical. In addition to our product solution, we have put in place processes to manage the efficacy of the solution and outlined the oversight and management of the process.



We appreciate involved stakeholders efforts to include manufacturers, legislators, distributors, retailers, and ultimate users. We look forward to our sharps lifecycle leadership in this area and anticipate a continued shift that will enable the industry to better manage the safe disposal of sharps. UltiMed will continue to be a leader in sharps lifecycle management and hope that others will do their part in minimizing the negative impacts of improper sharps disposal in California and beyond.

Best Regards,



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*Leader in Sharps Stewardship*

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## Section 1. Introduction

UltiMed, Inc. (UMI) is a leading manufacturer and distributor of sharps devices that are authorized for use in the United States (U.S.) and Canada. The company maintains a growing and sustained market for its sharps devices and has done so since its founding in 1988. With its corporate offices located in Excelsior, Minnesota and its manufacturing/operations facilities in De Smet, South Dakota and South Korea, UltiMed has established itself as a certified Good Manufacturing Practice company and is also ISO 13485:2016 certified.

In our concerted effort to maintain our presence and footprint in the State of California, the company proudly submits our stewardship plan which details our plan of operation to supply a sharps waste container and mail-back materials for home-generated sharps at no additional cost to the ultimate user. This effort is coordinated and implemented in complete compliance with California Senate Bill 212 (SB-212), *Solid Waste: Pharmaceutical and Sharps Waste Stewardship*. Our stewardship plan details our full strategy for maintaining and adhering to SB-212 requirements wherever it affects our business practices and product distribution in the State.

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## Section 2. Contact Information

Selecting a qualified and experienced professional to spearhead our Program is important to meeting our goals and objectives. As such, Mr. Jim Erickson, President and Chief Executive Officer (CEO) of UltiMed, has been identified and selected as the company's primary contact and responsible party for submitting and overseeing UltiMed's stewardship plan. Mr. Erickson has led and directed UltiMed since 2003 as one of UltiMed's key professionals. With a BBA from University of Notre Dame and MBA from the Kellogg School of Management at Northwestern University, Mr. Erickson is well versed in understanding the intricacies of our business. Furthermore, he maintains almost 25 years of executive management and finance experience and has demonstrated, over the years, his excellent capacity to consistently lead the company in delivering quality products.

Mr. Erickson's contact information is listed below.

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## Section 3. Covered Entities

UltiMed is the sole and only covered entity. Because UltiMed is positioned as a leader in supplying the only all-in-one solution to address proper sharps containment and disposal, we have the uncommon capability to act as our own covered entity. Our UltiGuard Safe Pack solution provides pharmacies and ultimate users an all-in-one solution for dispensing of pen needles or syringes in a single, self-contained, puncture-resistant, Food and Drug Administration (FDA)-cleared sharps container. Currently, UltiMed is the only sharps manufacturer that provides a sharps waste container for the safe disposal of used sharps at no additional cost to the ultimate user.

Mr. Erickson is designated and will act as the covered entity's point of contact (POC). He can be reached at:

**Jim Erickson, President & CEO**  
**UltiMed, Inc.**

Program Operator: UltiMed, Inc.

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## Section 4. List of Sharps Sold

UltiMed sharps devices, sold and distributed for human use, are vast and fully compliant with FDA requirements. Though vast, the company continuously maintains a high standard for delivering precision and well-designed products that are meticulously manufactured and quality controlled to one of the highest standard allowable. It should be noted that all our sharps devices, including those products to be sold by UltiMed as part of the stewardship plan, center around consumer needs:

- All needles are silicone coated and micro-polished for comfort and easy glide into the skin.
- Laser technology is used for quality assurance/quality control (QA/QC) inspection efforts for all manufactured needles.
- Bold unit dose markings and large flanges are incorporated in the design of syringes to provide better dosing accuracy and control.
- Pen needles are compatible with most pen injector devices.
- All-in-one sharps container allows for convenient dispensing and safe disposal of used needles.

As part our stewardship plan, UltiMed, as the covered entity, will incorporate select UltiGuard Safe Pack pen needle and syringe products that include a sharps waste container and mail-back materials at no cost to the ultimate user. These fully-compliant products are listed in [Table 1](#) (page [13](#)) and [Table 2](#) (page [14](#)).

**Table 1. UltiMed Mail-back U-100 UltiGuard Safe Pack Insulin Syringes**

Product Description	Barrel Size	Needle Gauge	Needle Length	Count/Selling Unit	Product Number	National Drug Code/Human Readable Interpretation Number	UPC Number
3/10 mL – 31G x 8mm (5/16")	3/10 mL	31G	8mm (5/16")	100	912439	08222-1243-95	3-57515-12439-5
1/2 mL – 31G x 8mm (5/16")	1/2 mL	31G	8mm (5/16")	100	912459	08222-1245-93	3-57515-12459-3
1 mL – 31G x 8mm (5/16")	1 mL	31G	8mm (5/16")	100	912419	08222-1241-97	3-57515-12419-7
3/10 mL – 30G x 12.7 mm (1/2")	3/10 mL	30G	12.7mm (1/2")	100	912335	08222-1233-50	3-57515-12335-0
1/2 mL – 30G x 12.7mm (1/2")	1/2 mL	30G	12.7mm (1/2")	100	912355	08222-1235-58	3-57515-12355-8
1 mL – 30G x 12.7mm (1/2")	1 mL	30G	12.7mm (1/2")	100	912315	08222-1231-52	3-57515-12315-2

**Table 2. UltiMed Mail-back UltiGuard Safe Pack Pen Needles**

Product Description	Barrel Size	Needle Gauge	Needle Length	Count/Selling Unit	Product Number	National Drug Code/Human Readable Interpretation Number	UPC Number
32G x 4mm (5/32") Micro	-	32G	4mm (5/32")	100	712543	08222-1254-39	3-57515-12543-9
31G x 5mm (3/16") Mini	-	31G	5mm (3/16")	100	712553	08222-1255-30	3-57515-12553-0
31G x 6mm (1/4") Mini	-	31G	6mm (1/4")	100	712563	08222-1256-37	3-57515-12563-7
32G x 6mm (1/4") Mini	-	32G	6 mm (1/4")	100	712562	08222-1256-20	3-57515-12562-0
31G x 8mm (5/16") Short	-	31G	8mm (5/16")	100	712583	08222-1258-35	3-57515-12583-5
29G x 12.7mm (1/2") Original	-	29G	12.7mm (1/2")	100	712512	08222-1251-25	3-57515-12512-5

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## Section 5. State Agency Compliance Certifications

UltiMed acknowledges that our sharps products, stipulated under this stewardship plan, must comply with local, state, and federal requirements. Our stewardship plan has been accepted by the:

- California State Board of Pharmacy, certification received on September 23, 2021 (see [Appendix B](#)), and
- California Department of Public Health, certification received on October 1, 2021 (see [Appendix C](#)).

## Section 6. Program Budget and Funding

UltiMed is a multi-million-dollar company, recording profits year over year since 1992 with the capacity to sustain its position as a future SB-212 covered entity. With a strong financial history, UltiMed is prepared financially to establish and maintain a sustainable and acceptable stewardship plan to be initiated in the State of California. Specifically, the anticipated budget for our stewardship plan addresses all the pertinent needs required to promote the proper use and disposal of applicable UltiGuard Safe Pack pen needles and syringes. [Table 3](#) on page [18](#) details how our company plans to budget and finance our stewardship plan. Our stewardship plan budget allocates funds towards consumer and pharmacy personnel education as it relates to the proper use and disposal of pen needles and syringes.

Estimated capital and annual costs to implement and operate the Program are listed separately and include the following items:

1. **Capital Costs:** Program setup includes the initial costs associated with the implementation, vendor setup, stewardship plan, and education and outreach.
2. **Collection, Transportation, Disposal Costs:** Expenses associated with managing the mail-back program, USPS shipping fees, and fees associated to dispose of the used sharps.
3. **Education & Outreach Costs:** Includes marketing to retail pharmacies and ultimate users to educate them on the compliant products under the UltiMed SB-212 stewardship plan. Marketing materials may include flyers, brochures, in-store signage, and other collateral as required by the market.
4. **Grants, Loans, Sponsorship Costs:** Grants, loan expenses, or sponsorships may be used when appropriate for market outreach and education. This may include, but is not limited to organizations, such as the American Diabetes Association or the American Association of Diabetes Educators.
5. **Independent Financial Audit Costs:** UltiMed anticipates some level of expenses with our current 3rd party audit provider, McGladrey LLC, as it relates to SB-212 compliance.
6. **Departmental Administration Fee:** UltiMed anticipates departmental administrative fees associated with the implementation of SB-212 and the ongoing management of the Program.

UltiMed is operating the Program on its own through the general operation of the overall business. Therefore, the estimated recommended funding level is equal to the estimated annual budget set forth.

UltiMed has recommended a reserve in the amount of 50% of the recommended annual funding level. This would equal approximately 6 months of the annual estimated costs



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associated to operate the stewardship plan. UltiMed believes this is more than sufficient to cover any stewardship plan obligations. This reserve capacity will be in the form of access to liquidity through either cash reserves, debt revolver capacity, or short-term assets.

**Table 3. UltiMed Stewardship Program Annual Budget**

	2021	2022	2023	2024	2025
<b>Recommended Funding Level (CCR 18973.6)</b>	<b>\$175,802</b>	<b>\$152,750</b>	<b>\$402,363</b>	<b>\$436,467</b>	<b>\$492,937</b>
<b>Stewardship Program Costs (CCR 18973.6)</b>					
<b>Stewardship Capital Costs (CCR 18973.6)</b>					
Total Capital Costs	\$120,802	\$0	\$0	\$0	\$0
<i>Program setup cost includes initial costs associated with process implementation, vendor setup, stewardship plan, and education and outreach.</i>					
<i>Product setup costs include items related to developing the mail-back product line (i.e., packaging, labeling, education, Website, and inventory).</i>					
<b>Stewardship Recurring Costs (CCR 18973.6)</b>					
Collection, Transportation, Disposal	0	82,000	246,000	282,900	325,335
<i>Expenses associated with managing the mail-back program; is determined by quantity of product distributed (based on expected volumes distributed).</i>					
<i>USPS and disposal fees are generated after a sharps is returned (based on expected volumes distributed).</i>					
<i>Volumes for mail-back processing, USPS, and disposal fee is based on compliance (based on expected volumes distributed).</i>					
Administrative Costs	20,000	23,000	26,450	30,418	34,980
<i>Overall management of the program to include compliance efforts, analytics, and corrective actions.</i>					
<i>Overall management of the Website and toll-free telephone number and associated activities.</i>					
Education & Outreach	30,000	34,500	39,675	45,626	52,470
<i>Includes marketing to wholesalers and retailers; is associated with California SB-212 education.</i>					
<i>Includes marketing materials used to educate the market on compliant products under the UltiMed stewardship plan.</i>					
<i>Continued development of marketing materials for the implementation of the education and outreach (such as flyers, education, informationals, and diagrams).</i>					
Grants, Loans, Sponsorships	5,000	5,750	6,613	7,604	8,745
<b>Independent Financial Audit Expense (CCR 18973.6)</b>	0	7,500	8,625	9,919	11,407
<i>Estimate of additional work that may be required by UltiMed's third-party auditors to comply to SB-212 requirements.</i>					
<b>Departmental Administrative Fee (PRC 42034)</b>	0	0	75,000	60,000	60,000
<i>CalRecycle fees and/or other departmental administrative fees.</i>					
<b>Total</b>	<b>55,000</b>	<b>152,750</b>	<b>402,363</b>	<b>436,467</b>	<b>492,937</b>
<b>Total Annual Costs</b>	<b>\$175,802</b>	<b>\$152,750</b>	<b>\$402,363</b>	<b>\$436,467</b>	<b>\$492,937</b>
<b>Recommended Reserve Level Amount (CCR 18973)</b>	<b>\$87,901</b>	<b>\$76,375</b>	<b>\$201,182</b>	<b>\$218,234</b>	<b>\$246,469</b>
<i>Reserve amount equals 50% of the annual estimated funding level.</i>					

## Section 7. Policies and Procedures for Collecting, Tracking, and Managing Home-Generated Sharps Waste

Having been in business for more than three decades, UltiMed has always been conscientious and cognizant of the importance of managing and tracking the distribution, collection, and disposal of home-generated sharps waste. Policies, processes, and standard operating procedures (SOPs) that underscore the safe use and disposal of our sharps devices is vital to our continued progress. As a recognized ISO 13485:2016-compliant organization, we continuously develop customer-centered processes that promote on point post-delivery processes and end-to-end product distribution measures. Any noncompliance issues or willful negligence in adhering to established safety policies and processes are expeditiously remediated. Between our organization and PureWay Compliance, Inc., our waste service provider, we employ systematic procedures for safely and securely collecting, tracking, and managing sharps waste on multiple levels. From our Quality Management System (QMS) that addresses problematic sharps that fall into our defective waste category to PureWay's internal process for handling and tracking returned sharps, we make every effort to gather information and track details regarding the *lifecycle* of our sharps products. Procedures, such as our QMS controlled QP-013 procedural document, in conjunction with our product barcoding/lot numbering process, identify and mitigate the collection and disposal of sharps that may be defective. These procedures integrate defined information gathering procedures and root-cause analysis (RCA) problem solving techniques to ensure any product problems are resolved and not repeated. Likewise, PureWay, uses a barcoding system to log, track, and count sharps returned by the ultimate user, and their well-defined processes for safely disposing sharps waste is effective and proven.

Information provided in this section provides details on how we integrate safety procedures to ensure compliance to company and government agencies.

### 7.1. Sharps Waste Containers and Mail-back Material Distribution and Process

UltiMed has introduced a novel FDA-cleared Class II sharps waste container and executes a proven plan for distributing it, combined with mail-back materials to pharmacies and other retailers. Pioneering and engineering an all-in-one container design, our UltiGuard Safe Pack sharps waste container (see [Figure 1](#) on page [20](#)) allows the ultimate user to dispense and dispose of sharps devices. More importantly, this same all-in-one container can be returned to our final waste disposal service provider, PureWay, after all product is consumed or deemed unusable. UltiMed's forward thinking is also demonstrated in our first-class ISO-certified manufacturing and distribution operations which comprise third-party team members and teams from our own manufacturing operations based in De Smet, South Dakota. Notably, our product solution addresses the safety concerns

associated with proper sharps containment, while delivering products that are easy and convenient to prescribe, obtain, manage, and use.



*Figure 1. UltiMed's FDA-cleared Class II Medical Device Sample. UltiGuard Safe Pack Pen Needle (510K K081449, issued June 2008) and Insulin Syringe (510k K021983, issued September 2002).*

UltiMed introduced and began marketing its durable UltiGuard Safe Pack product line with a customer- and safety-centered concept in 2002. UltiGuard Safe Pack containers comprise a multi-piece, durable, self-enclosing plastic shell with two main compartments: A dispensing compartment for accessing new pen needles or syringes and a sealed disposal compartment for proper sharps containment. Each container comprises 100 pen needles or syringes with enough room in the disposal compartment to house all the used sharps. From one single container (the UltiGuard Safe Pack container), the ultimate user simply follows three steps for using the product:

1. Dispense sterile pen needles or syringes from the UltiGuard Safe Pack container whenever needed,
2. Dispose of the used sharps in the UltiGuard Safe Pack container after all product is consumed,

**Note:** UltiGuard Safe Pack products, included as part of our stewardship plan, ship with a 100-count supply of pen needles or syringes, as stipulated in [Table 1](#) on page 13 and [Table 2](#) on page 14. It should be noted that *all* UltiGuard Safe Pack containers provide ample room for the disposal of all used sharps that are included in product packaging. Ultimate users never have to dispose of used needles through any other means. Our product reinforces proper consumer behavior for disposing sharps directly in the UltiGuard Safe Pack container.

3. Return the UltiGuard Safe Pack container with all used sharps in the container's disposal compartment, using the provided mail-back materials enclosed in the product's original packaging.

UltiGuard Safe Pack is easy to use with little opportunity for ultimate user confusion. Everything needed to dispense and dispose of sharps waste is provided in the kit at no

additional cost to the ultimate user. Also, after the unit's supply is exhausted or no longer needed, everything needed to return the kit for proper disposal, instructions for use, a prepaid return shipping box, and tracking manifest are provided (in English and Spanish) with the product's original packaging. UltiGuard Safe Pack provides a simple and convenient solution for returning the sharps waste to UltiMed's disposal representative for proper disposal.

Lastly, our stewardship plan allots budgetary funds for the free mail-back of used sharps using a prepaid, preaddressed USPS mail label. Refer to [Table 3](#) and page [18](#) for more information on our funding plan.

### **7.1.1. UltiMed Mail-back Material Distribution Amounts**

Endeavoring to comply with local and federal regulations, we employ a concerted effort to combine and emphasize efficiency, convenience, and simplicity as part of our stewardship plan. Our process for distributing a sharps waste container and mail-back materials is built into our manufacturing process at our De Smet, SD manufacturing facility. First, each container is packed with 100 new pen needles or syringes, precisely enough to fully fill the disposal compartment of the container.



*Figure 2. UltiGuard Safe Pack Packaging and Mail-back Box*

Next, all mail-back materials are assembled in our ready-to-sell packaging, allowing us to economize efforts and minimize production cost. Allowing ultimate user convenience, we provide everything needed to return the kit for proper disposal—from the prepaid and preaddressed return shipping box (see [Figure 2](#)) to the plastic reclosable plastic bag for the sharps waste container and shipping tape. To offset and deter ultimate user reluctance, all materials are included in our off-the-shelf, branded package. The kit includes easy-to-follow instructions ([Figure 3](#) on page [22](#)) that exhibit warnings relative to mandated requirements for the safe disposal of consumed sharps and step-by-step instructions for returning the sharps waste container. To further ensure inclusivity, all included materials are translated in Spanish. UltiMed's all-in-one kit, dispensed at the point-of-sale, combines pen needles or syringes, a sharps waste container, and mail-back materials to the ultimate user in a simple easy-to-use solution at no additional cost.



Figure 3. UltiGuard Safe Pack Mail-back Instructions

### 7.1.2. Sharps Waste Disposal Information

UltiMed knows that necessary information on proper sharps waste entails:

- Detailing complete and thorough instructions on how to use our product, which includes instructions for proper sharps disposal,
- Communicating the importance of adhering to local and federal laws relative to the proper disposal of sharps, and
- The consequences for disregarding local and federal mandates for proper sharps containment and disposal.

UltiMed provides ultimate users with beneficial and timely information, both in English and Spanish, for the proper use and disposal of sharps. UltiGuard Safe Pack materials include:

- Instructions for use
- Prepaid and preaddressed return shipping box
- Tracking manifest

- Reclosable plastic bag
- Tape strip

**Note:** Since one of California's primary ethnic groups is Spanish speaking, it should be noted that we translate packaging and materials in Spanish as a minimum standard, exceeding industry standards for English-only packaging and materials. This packaging feature is offered as a value-add component for ultimate users and pharmacists, who assist ultimate users in using and understanding the use of our UltiGuard Safe Pack products. Because we offer all materials in Spanish, in addition to English, our company and our dispensing pharmacies are better able to assist Spanish speaking communities, and consumers who speak in Latin-based languages and can, in most cases, decipher Spanish instructions as a result of the language similarities. With our product and materials, English-only speaking liaisons can overcome communication gaps among Spanish (and Latin-based) speaking groups and point users to product packaging for all product explanations.

Noncompliance warnings associated with sharps disposal mandates are printed on containers, outer packaging, and mail-back materials. [Table 4](#) on page [23](#) and [Table 5](#) on page [24](#) lists the warnings noted on production materials and instructional notations for properly disposing of sharps devices.

**Table 4. Printed Noncompliance Warnings on UltiGuard Safe Pack Pen Needles**

Product Location	Warning Type	Warning Verbiage
Container Booklet (adhered to UltiGuard sharps container)	Instruction for use and disposal	"Take a new needle from the side. After use, safely dispose into the top of the sharps container."
Container Booklet (adhered to UltiGuard sharps container)	Booklet biohazard warning	"Dispose according to local regulations."
Container Booklet (adhered to UltiGuard sharps container)	Instructional	"After giving the injection, leave pen needle on pen injector. Carefully insert pen needle tip into center of red opening on top of the UltiGuard® Safe Pack."
Container Booklet (adhered to UltiGuard sharps container)	Instructional	Illustrative diagram, showing step-by-step, how to dispose of used pen needles into the sharps disposal container compartment.
Mail-back Shipping Box	Biohazard warning printed on the side panel	"Dispose according to local regulations."
Mail-back Package Components Brochure	Disposal warning	"Failure to properly complete and sign the tracking manifest may result in enforcement under state, local, and federal rules and regulations and additional fees may be applied."
Mail-back Package Components Brochure	Instruction for sharps use and disposal	"When you have used all the pen needle supply, place the Safe Pack into the re-closable plastic bag and return to the brown inner box by following the instructions on the reverse side of this page."



**Table 5. Printed Noncompliance Warnings on UltiGuard Safe Pack Syringes**

Product Location	Warning Type	Warning Verbiage
Container Booklet (adhered to UltiGuard sharps container)	Booklet biohazard warning	"Dispose according to local regulations."
Container Booklet (adhered to UltiGuard sharps container)	Instructional	"After giving the injection, carefully insert insulin syringe into the center opening on top of the UltiGuard Safe Pack."
Container Booklet (adhered to UltiGuard sharps container)	Instructional	Illustrative diagram, showing step-by-step, how to dispose of used syringe needles into the sharps disposal container compartment.
Individual Syringe Package	Instructional	"To prevent misuse, dispose of syringe in sealable puncture proof container."
Syringe	Instructional	"...Only use once and destroy."
Mail-back Shipping Box	Biohazard warning printed on the side panel	"Dispose according to local regulations."
Mail-back Package Components Brochure	Disposal warning	"Failure to properly complete and sign the tracking manifest may result in enforcement under state, local, and federal rules and regulations and additional fees may be applied."
Mail-back Package Components Brochure	Instruction for sharps use and disposal	"When you have used all the syringe needle supply, place the Safe Pack into the re-closable plastic bag and return to the brown inner box by following the instructions on the reverse side of this page."

All packaging and instructional brochures are provided to the ultimate user at the point-of-sale inside product packaging. Instructions and additional information with regards to proper disposal of sharps waste are also available on our [Safe Needle Disposal](#) website.

### 7.1.3. Sharps Waste Container Labelling

As a program operator providing a sharps waste container and mail-back materials in an all-in-one kit, UltiMed demonstrates availability to ultimate users by providing means for them to easily contact us through our dedicated toll-free customer service telephone number and Website. Our [Safe Needle Disposal](#) website, along with our toll-free number for contacting us, is printed on the outer packaging of all related products. Our contact information further details the days and hours of operation for ultimate users should they need to contact us. Instructional booklets adhered to our containers list our Website address and toll-free telephone number as well.

See the [Material Localization](#) section on page [34](#) for more information.

### 7.1.4. Prepaid Mail-back Postage

Maximizing the probability of the return of used sharps is paramount to the success of our disposal solution for all used sharps. Coordinating mail-back and prepaid postage with the US Postal Service (USPS) in advance provides ultimate users with a no-hassle mail-back container that is factory packed with USPS prepaid materials (See [Figure 4](#) for a thumbnail of UltiMed's coordination letter and [Appendix A](#) on page [40](#) for a full-size copy



of the coordination letter.) Implementing prepaid postage as part of our mail-back solution increases the probability ultimate users will return it for proper disposal.

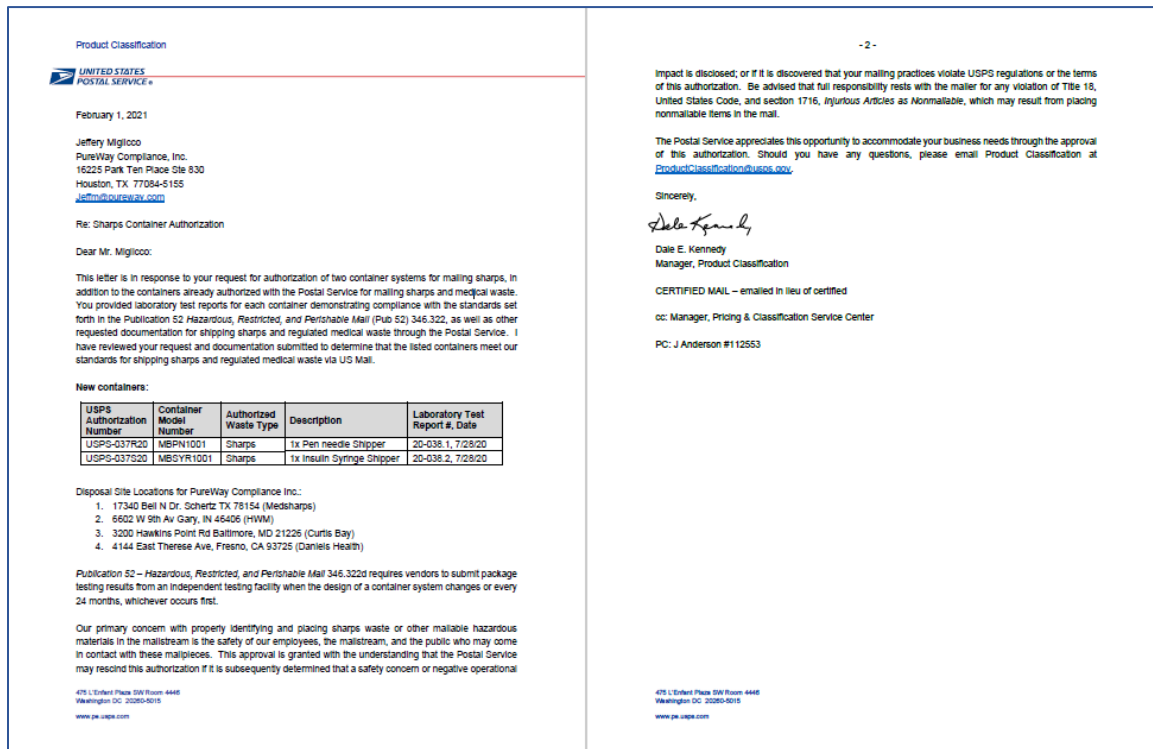


Figure 4. Prepaid USPS Coordination and Approval Letter

## 7.2. Collection, Transportation, and Disposal System Records

UltiMed plans to generate collection, transportation, and disposal records for the approved products included in our stewardship plan, including the following:

- Tracking manifest (receipt of return home-generated return mailings)
- USPS return shipment label origination
- Final disposal documentation

These records will be housed in our service provider's information technology system and can be made available to the department by contacting the covered entity's POC.

See [UltiMed Home-Generated Sharps Waste Collection and Transport Service Providers](#) on page 25 for more information.

## 7.3. UltiMed Home-Generated Sharps Waste Collection and Transport Service Providers

UltiMed employs reputable transportation services and uses highly qualified disposal service providers that have proven to be reliable and predictable. USPS is a stable

establishment and has proven, even during current crises, to be reputable, transporting our materials and information in a timely manner. PureWay Compliance, Inc., as our sharps disposal service provider, has been in business for approximately 15 years. The company has partnered with UltiMed successfully and remains a solid, long-term provider, supporting UltiMed's sharps disposal needs. Working with our disposal service provider, our team has identified established treatment and disposal locations (see [Table 6](#) through [Table 8](#)). The addresses of treatment and disposal locations are determined during the manufacturing process and is specified on the pre-paid shipping label. Upon arriving at a treatment facility, mail-back packages are scanned for receipt verification, and weighed. Sharps are autoclaved or incinerated. The sterilized autoclaved materials are then disposed of in a landfill, as solid waste, in compliance with all applicable laws, regulations, and other requirements.

**Note:** The facilities listed in [Table 7](#) are those contracted with UltiMed's disposal service provider, PureWay Compliance, Inc. Mail-back packages are sent to these facilities for treatment and/or final disposal. Initially, the mail-back packages will be sent to the Medsharps treatment facility in Schertz, TX for autoclaving. The autoclaved waste will then be transported to the Tessman Road landfill for final disposal. As the program evolves, PureWay may use other contracted facilities for sharps disposal and destruction.

**Table 6. UltiMed Transportation and Sharp Disposal Service Providers**

	Transportation/Delivery Provider	Sharps Disposal Service Provider
<b>Provider Name</b>	United States Postal Service (USPS)	PureWay Compliance, Inc.
<b>Provider Mailing and Physical Address</b>	475 L'Enfant Plaza SW Washington, DC 20260-0004	16225 Park Ten Place, #830 Houston, TX 77084

**Table 7. Contracted and Permitted Treatment Facilities**

Provider Name	Healthwise Services	Medsharps	HWM	Curtis Bay
<b>Provider Mailing and Physical Address</b>	4800 E. Lincoln Avenue Fowler, CA 93625	17340 Bell North Drive Schertz, TX 78154	6602 W. 9th Avenue Gary, IN 46406	3200 Hawkins Point Road Baltimore, MD 21226

**Table 8. Disposal Facilities**

Provider Name	Tessman Road Landfill	Newton County Landfill	American Avenue Landfill	King George Landfill
<b>Provider Mailing and Physical Address</b>	7000 IH 10 East San Antonio, TX 78219	2266 E 500 South Road Brook, IN 47922	18950 W American Avenue Kerman, CA 93630	10376 Bullock Drive King George, VA 22485

## 7.4. Alternate Sharps Waste Collection Methods

UltiMed proposes a complete solution, offering ultimate users prepaid postage for mailing back used sharps and sharp containers. As such, UltiMed is not implementing a

receptacle-based program using authorized and approved home-generated sharps consolidation points under the Medical Waste Management Act. UltiMed's solution is a one-stop solution, making our mail-back program economical and convenient.

#### **7.4.1. Secure Receptacle Collection Process**

See [Alternate Sharps Waste Collection Methods](#) on page [26](#).

##### **7.4.1.1. Name of Consolidation Point**

See [Secure Receptacle Collection Process](#) on page [27](#) for more information.

##### **7.4.1.2. Collection Receptacle Monitoring and Service Scheduling**

See [Secure Receptacle Collection Process](#) on page [27](#) for more information.

##### **7.4.1.3. Consolidation Point Funding**

See [Secure Receptacle Collection Process](#) on page [27](#) for more information.

##### **7.4.1.4. Standard Operating Procedures for Reporting Safety and Security Incidents**

Policies, processes, and standard operating procedures (SOPs) that address proper product management and incident resolution is important to our continued success. As a recognized ISO 13485:2016-compliant organization, we maintain customer-centered processes that promote and support established methods for reporting incidents that could or would impact the safe use and secured handling of all sharps devices. We and our partners also employ state-of-the-art barcoding and lot numbering processes and systems for tracking devices. Specifically, dedicated program teams are organized internally to manage Quality Management System (QMS) processes and procedures. Our Quality Management System addresses incidents associated with sharps devices, with a hierarchical structure for receiving and communicating all product issues externally and internally. Procedures, such as our QMS-controlled QP-013 procedural document, identify and mitigate incidents. These and other procedures integrate defined information gathering procedures and root-cause analysis (RCA) problem solving techniques to ensure full resolution, product alignment, and product compliance for all products delivered to ultimate users.

In the case of a noncompliant event, UltiMed will initiate a Corrective and Preventative Action (CAPA) to determine the root-cause of the noncompliant event. UltiMed, as the program operator, will investigate for root-cause; modify procedures and protocols, as needed; and audit for effectiveness to mitigate future noncompliance issues relative to the stewardship plan.

#### **7.4.2. Managing Take-back Events**


See [Alternate Sharps Waste Collection Methods](#) on page [26](#).


## **7.5. Metrics for Measuring Home-Generated Sharps Waste Containers, Distributed Materials, and Returned Sharps Waste**

UltiMed and its sharps waste service provider, PureWay will track our products based on a goods sold model, linking our systems together for full visibility. UltiMed uses its Enterprise Resource Planning (ERP) system to fulfill sales orders to its customers. PureWay uses an Order Tracking System (OTS) to scan and upload documentation received from the ultimate user for home-generated sharps waste destruction. The returned product is equipped with a tracking manifest barcode and USPS prepaid return shipping label barcode. The tracking manifest (see [Figure 5](#) on page [29](#)) and USPS prepaid return shipping labels are tagged with unique identifiers. Upon arriving at a treatment facility, mail-back packages are scanned for receipt verification and weighed. We will also track, and report sharps waste reimbursed to local hazardous household waste facilities using weight as the key metric. UltiMed will maintain and archive records within the company's information technology system in a dedicated drive, secured through user and group level security, and back up the system on a predetermined schedule. These records can be made available to the department by contacting the covered entity's point of contact (POC).

UltiMed will collect data to create measurable metrics. Specifically, we will track:

- Units of covered product distributed into the State of California
- Units and weight of covered product returned through USPS to disposal facilities
- Weight of home-generated sharps waste from local household hazardous waste facilities requested for reimbursement


**ULTIMED**  
 INCORPORATED

  
 18UM1001

## COMPLIANCE TRACKING MANIFEST

### DECLARACIÓN DE SEGUIMIENTO DE CUMPLIMIENTO

**MUST COMPLETE QUESTIONS 1-8 FOR RETURN SHIPPING**  
**ES OBLIGATORIO CONTESTAR LAS PREGUNTAS 1-8 PARA ENVÍOS EN CASO DE DEVOLUCIÓN**

Please CLEARLY fill in all of your information below. Upon completion, remove the Dark Yellow "Customer" (bottom) copy of this document and retain for your records. Upon completion, fold and place the remaining copies back in the plastic bag on the side of the prepaid return shipping box and seal. Please refer to the instructions included with your system for more details. If you have any questions, please call 1-844-8SHARPS (1-844-874-2777).

Especifique CLARAMENTE toda su información a continuación. Al terminar, separe de este documento la copia de color amarillo oscuro correspondiente al "Cliente" ("Customer", al fondo) y guárdela para su referencia. A continuación, doble las copias restantes y póngalas de vuelta en la bolsa de plástico al costado de la caja de transporte de la devolución con franqueo prepago. Selle la caja. Para más información, consulte las instrucciones incluidas con su sistema. Si tiene alguna pregunta, llame al 1-844-8SHARPS (1-844-874-2777).

I certify that all containers within this system have been approved for the mailing of "regulated medical waste-sharps" and have been prepared in accordance with the direction for that purpose. I certify that this system does not contain excess liquids or non-mailable materials in violation of the applicable Postal Service regulations. I certify that the contents of this consignment are 1) fully and accurately described below by proper shipping name, 2) are classified, packed, marked and labeled, and 3) in proper condition for carriage by air according to national regulations. LASTLY, I AM AWARE THAT FULL RESPONSIBILITY RESTS WITH THE (GENERATOR) MAILER FOR ANY VIOLATION OF 18 USC 1716 WHICH MAY RESULT FROM PLACING PROHIBITED AND IMPROPERLY PACKED ITEMS IN THE MAIL.

Certifico que todos los recipientes contenidos dentro de este sistema están aprobados para el envío por correo de "objetos punzocortantes-desperdicios médicos reglamentados" y que se prepararon conforme a las instrucciones para tal fin. Certifico que este sistema no contiene un exceso de líquidos ni materiales sujetos a prohibición de envío por correo que violen los reglamentos aplicables del Servicio Postal. Certifico que el contenido de esta mercancía: 1) se describe a continuación, plenamente y con exactitud, con su nombre de envío adecuado, 2) está clasificado, embalado, marcado y rotulado, y 3) cumple con las debidas condiciones para el transporte aéreo establecidas en los reglamentos nacionales. POR ÚLTIMO, SOY CONSCIENTE DE QUE EL REMITENTE (GENERADOR) ASUME LA RESPONSABILIDAD TOTAL Y ABSOLUTA DE TODA VIOLACIÓN DEL CAPÍTULO 18 DEL CÓDIGO DE ESTADOS UNIDOS (18 USC 1716) QUE RESULTE DE PONER EN EL CORREO ARTÍCULOS PROHIBIDOS E INCORRECTAMENTE EMBALADOS.

1. CONTACT NAME / NOMBRE DEL CONTACTO _____	
2. ADDRESS / DIRECCIÓN _____	3. CITY / CIUDAD _____
4. STATE / ESTADO _____	5. ZIP / CÓDIGO POSTAL _____
6. PHONE / TELÉFONO _____	
7. SIGNATURE / FIRMA _____	8. DATE SHIPPED / FECHA DEL ENVÍO _____

**DESCRIPTION OF CONTENTS / DESCRIPCIÓN DEL CONTENIDO:**  
 Regulated Medical Waste-Sharps / Objetos punzocortantes-desperdicios médicos reglamentados

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**TO BE COMPLETED BY TREATMENT FACILITY ONLY**

I certify that the contents of this container have been received, treated and processed in accordance with local state and federal regulations.

TREATMENT FACILITY MANAGER PureWay

**In case of emergency or the discovery of damage or leakage call 877-765-3030**  
**En caso de emergencia o si se descubren daños o fugas, llame al 877-765-3030**

For assistance, visit our website at [disposemyneedles.com](http://disposemyneedles.com) or contact us at 1-844-8SHARPS (1-844-874-2777).  
 Si necesita asistencia, visite nuestro sitio web ([disposemyneedles.com](http://disposemyneedles.com)) o llámenos al 1-844-8SHARPS (1-844-874-2777).

White: Treatment Facility | Light Yellow: Shipper | Pink: UltiMed | Dark Yellow / Amarillo oscuro: Customer / Cliente

MECTM/REV10/0020-2020-02

Figure 5. UltiMed Mail-back Compliance Tracking Manifest Sample

## 7.6. Metrics for Measuring Home-Generated Sharps Waste Collection

Refer to Section [7.5, Metrics for Measuring Home-Generated Sharps Waste Containers, Distributed Materials, and Returned Sharps Waste](#), on page [28](#) for more information.

## 7.7. Metrics for Measuring Sharps Waste by Household Hazardous Waste Facilities Operated by Local Agencies

Refer to Section [7.5, Metrics for Measuring Home-Generated Sharps Waste Containers, Distributed Materials, and Returned Sharps Waste](#), on page [28](#)

## 7.8. Management and Handling of Stewardship Plan Noncompliance Issues

UltiMed is both an ISO 13485:2016 and a Medical Device Single Audit Program (MDSAP) certified medical device manufacturer. Our manufacturing facility and devices are audited annually and meet all ISO 13485:2016 and MDSAP standards. Our QMS integrates

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robust complaint and Corrective and Preventive Actions (CAPA) programs, design controls, and Good Manufacturing Practice (GMP) manufacturing processes.

This stewardship plan will be added to our internal audit program. In the case of any noncompliant event, UltiMed will initiate a Corrective and Preventative Action (CAPA) process to determine the root-cause of the noncompliant event. UltiMed, as the program operator, will investigate for root-cause; modify procedures and protocols, as needed; and audit for effectiveness to mitigate future noncompliance issues relative to our plan.

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## Section 8. Local Agency Reimbursement

UltiMed will work to establish contacts at local household hazardous waste facilities and develop a process for reimbursement for the transportation and disposal of home-generated sharps. If a household hazardous waste treatment facility disposes of home-generated sharps waste, UltiMed will work with that agency to determine transportation and disposal costs and will reimburse the facility within 45 days of receipt of the local agency's invoice.

Requests from local agencies or an agent on their behalf must include an invoice with name and location of household hazardous waste facilities receiving reimbursement, date range, reimbursement total by facility, and total weight of home-generated sharps waste disposed as reported to UltiMed. and comply with the requirements in subsection (1)(F)(ii) of subdivision (d) of section 42032.2 of the Public Resources Code. UltiMed will ensure that a response to the request is completed within 14 days of receipt of the request and provide reimbursement for the removal from household hazardous waste facility(ies). Payment will be issued within 45 days of receipt of the local agency's invoice.

UltiMed will reimburse for the disposal of home-generated sharps waste collected from the local household hazardous waste facilities as often as required according to section 117904 of the Health and Safety Code or by the local enforcement authority.

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## Section 9. Ordinance Repeals

Should any local jurisdiction repeal its local stewardship program ordinance, UltiMed will expand the Program into that local jurisdiction within 270 days of the effective date of the local stewardship program ordinance repeal. During this period, UltiMed will transition the Program in the local jurisdiction, as applicable, and assess implementation requirements to expand the Program into the local jurisdiction, including the education and outreach program. Our stewardship plan and the products introduced under it provide a sharps waste container and mail-back materials in an all-in-one kit at no cost to the ultimate user. Pharmacies, or other retailers, can purchase the product from their preferred wholesaler and dispense it to the ultimate user as a kit, meeting the requirement of providing a sharps waste container and mail-back materials to the ultimate user at the point-of-sale.



## Section 10. Education and Outreach

### 10.1. Activities to Promote Awareness and Maximize User Participation

UltiMed's California education and outreach (E&O) tactics are focused on increasing awareness and adoption of desired practices and effectiveness of communication in the home-generated sharps ecosystem. The outreach tactics are created to support the Program's efforts around proper disposal of home-generated sharps leading to increased disposal of sharps by a medical waste treatment facility. The outreach plan is not designed to be directly correlated to operational program goals, such as increasing the disposal of home-generated sharps by a medical waste treatment facility. All education and outreach tactics are directly related to support providing information to the targeted audiences identified in the Plan and the legislation in order to encourage the behavior change necessary to meet the Program's goals. For example, as the Program informs more persons authorized to distribute and prescribe drugs about the new safe sharps disposal options, we expect that more sharps will be diverted from the landfill to medical waste treatment facilities for proper disposal.

**Retailers:** At first, retailers with pharmacies located in California will be contacted and alerted to the Program in general, and to its requirements. The focus for retailers is to provide them information about the legislation and collateral (signs, brochures, fact sheets) that explains the importance of proper disposal of home-generated sharps and its advantages to retailers and their customers. The tactics will also include direct outreach to pharmacies and pharmacy personnel in the State of California through a partnership with the California Pharmacists Association (CPhA) and Pharmacy Technician Certification Board (PTCB).

**Distributors:** Pharmacy distributors who service pharmacies located in California will be contacted and alerted of the Program and its requirements. The focus for distributors is to provide them information about the legislation and explain the importance of distributing only approved, compliant products to customers they service in California. This information will be communicated to the distributor's corporate category management personnel, and regional sales teams through webinars, newsletters, expos, and other public events.

The education and outreach materials to promote the Program to ultimate users for hospitals, pharmacies, and other locations and persons authorized to prescribe drugs, including pharmacies, pharmacists, ultimate users, and others, as necessary, will:

- Include educational webinars.
- Include printed materials and signage.
- Be free of charge.

## 10.2. Material Localization

UltiMed will provide educational and outreach materials to entities participating in the Program, and upon request distribute materials to persons authorized to prescribe drugs, hospitals, pharmacies, pharmacists, ultimate users, and others, as necessary. The education and outreach materials will be translated into English and Spanish when provided as printed hard copy. The printed materials will feature universally recognized translation icons that direct ultimate users to the Website to view or print translated documents. UltiMed's Website and Call Center will support all the languages specified per the most recent available Section 203 of the Voting Rights Act and state Elections Code, Section 14201. California Voting Rights Act and State Elections Code language requirements account for local demographics consistent with Section 7295 of the Government Code. UltiMed's Website will provide translations in over 100 languages, consistent with Section 7295 of the Government Code, which requires that any materials explaining services available to the public be translated into non-English languages spoken by a "substantial number of the public."

## 10.3. Website and Website Localization

UltiMed has developed a responsive Web design (RWD) that creates dynamic changes to the appearance of the Website, depending on the screen size and orientation of the device being used to view it, including mobile. Our Americans with Disabilities Act (ADA) compliant Website will include instructions for safe sharps handling and a submission form for the ultimate user to request a sharps waste container and mail-back materials. Information for languages suited to local demographics is summarized in Section [10.2](#). Refer to Section [10.2](#) for more information on Website localization.

## 10.4. Toll-free Telephone Number and Customer Support

UltiMed's Call Center will serve as an option for ultimate users to request sharps mail-back replacement materials and obtain information about the program. The Call Center will provide:

- A human representative to receive requests for services and questions about the program.
- A human representative who will assist the English-speaking ultimate users. Non-English-speaking ultimate users will provide their language preference and be connected to a live interpreter.
- Teletype services for hearing- and speech-impaired ultimate users.
- Instructions for safe handling and proper disposal of home-generated sharps waste.

## 10.5. Education and Outreach Metrics

Metrics will be established to evaluate the performance of the education and outreach provided to ultimate users and pharmacists. Customer education is to be offered formally and informally. Formal training is provided at a pharmacy level, where pharmacists work with ultimate users to help them use and manage the container and other sharps devices. However, customers and pharmacists will also receive a level of education by contacting our customer service representatives through our dedicated toll-free telephone number to obtain product use information. On this level, UltiMed tracks the level and type services provided to the various consumer types categorically. Outside of toll-free telephone assistance, UltiMed provides informal training through its Website where users can access applicable pages for self-paced instruction. As a company, UltiMed tracks traffic to our Website and Website pages. It is our goal to ensure that all mediums for administering customer education is easily obtainable and second to that, is to make sure we, as a company, are identifying and properly handling frequent customer trends and product questions.

From the information gathered during the aforementioned activities, UltiMed will collect the following data to create measurable metrics:

- Track units of covered product distributed into the State of California
- Track units and weight of covered product returned through USPS to disposal facilities
- Track the weight of home-generated sharps waste from local household hazardous waste facilities requested for reimbursement
- Track pharmacy locations that stock the product
- Track Website traffic and usage
- Track the quantity and/or number of impressions for program marketing and advertising

With this information, UltiMed will use the following metrics to assess the Program:

- **Program Usage Metric:** Units returned through the USPS, divided by units distributed
- **Accessibility Metric:** Number of pharmacy locations that have access to the approved product, divided by the total number of pharmacy locations in the State of California
- **Penetration Metric:** Number of pharmacy locations that distribute the approved product, divided by the total pharmacy locations that have access to it

## 10.6. Distinguishing Covered and Non-Covered Products

Materials and instructions provided with our UltiGuard Safe Pack products specifically stipulate that all UltiGuard Safe Pack sharps are developed for use in the UltiGuard Safe

Pack container *only*. Importantly, this information is available to pharmacists and ultimate users alike.

Ultimate users will use the mail-back material provided with our product. The UltiGuard Safe Pack sharps container is designed only to receive those sharps dispensed from the selfsame container.

## **10.7. Section 42031.6(b) Public Resource Code Compliance**

Understandably so, Section 42031.6(b) of the California Public Resources Code states that program operators are not to promote, under its educational and outreach programs, the disposal of a covered product in an inconsistent manner with the services offered to the ultimate user under a stewardship program. As the program operator, UltiMed will make all efforts to ensure that only those products included in our approved stewardship plan are distributed into the State of California. This includes working with the major pharmacy retailers and wholesalers to block the sale of noncompliant product into the State of California. In addition to blocking the sale of noncompliant product, all marketing education and outreach will only promote the approved SB-212 compliant product and address the proper method to use the sharps container and mail-back solution.

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## Section 11. Coordination Efforts

Should there be multiple approved program operators, UltiMed will work together with the other approved program operators to ensure the public and all program participants do not encounter confusion. UltiMed will coordinate with other program operators to ensure consistent messaging regarding home-generated sharps disposal, statistics about the dangers of home-generated sharps waste in the waste-stream, and other program advocacy. UltiMed strives to conduct its coordination with other program operators with a goal of fair and equitable division of resources.

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## Section 12. Loans, Sponsorships, Reimbursements, and Other Incentive Processes

Grants, loan expenses or sponsorships may be used when appropriate for market outreach and education. This may include, but is not limited to organizations, such as the American Diabetes Association or the American Association of Diabetes Educators.

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## Section 13. Service Provider Selection Processes

UltiMed fully vets all service providers for integrity, stability, value, and quality of service. Specifically, service providers maintain the customary arm's length status to prevent biased arrangements and promote integrity. Furthermore, the negotiation of terms and pricing among possible and applicable service providers helps us to select only those entities that meet predetermined criteria to ensure a high quality of service.

## **Appendix A. Actual Prepaid USPS Coordination and Approval Letter**



## Product Classification



February 1, 2021

Jeffery Miglicco  
 PureWay Compliance, Inc.  
 16225 Park Ten Place Ste 830  
 Houston, TX 77084-5155  
[Jeffm@pureway.com](mailto:Jeffm@pureway.com)

Re: Sharps Container Authorization

Dear Mr. Miglicco:

This letter is in response to your request for authorization of two container systems for mailing sharps, in addition to the containers already authorized with the Postal Service for mailing sharps and medical waste. You provided laboratory test reports for each container demonstrating compliance with the standards set forth in the Publication 52 *Hazardous, Restricted, and Perishable Mail* (Pub 52) 346.322, as well as other requested documentation for shipping sharps and regulated medical waste through the Postal Service. I have reviewed your request and documentation submitted to determine that the listed containers meet our standards for shipping sharps and regulated medical waste via US Mail.

### New containers:

USPS Authorization Number	Container Model Number	Authorized Waste Type	Description	Laboratory Test Report #, Date
USPS-037R20	MBPN1001	Sharps	1x Pen needle Shipper	20-038.1, 7/28/20
USPS-037S20	MBSYR1001	Sharps	1x Insulin Syringe Shipper	20-038.2, 7/28/20

### Disposal Site Locations for PureWay Compliance Inc.:

1. 17340 Bell N Dr. Schertz TX 78154 (Medsharps)
2. 6602 W 9th Av Gary, IN 46406 (HWM)
3. 3200 Hawkins Point Rd Baltimore, MD 21226 (Curtis Bay)
4. 4144 East Therese Ave, Fresno, CA 93725 (Daniels Health)

*Publication 52 – Hazardous, Restricted, and Perishable Mail* 346.322d requires vendors to submit package testing results from an independent testing facility when the design of a container system changes or every 24 months, whichever occurs first.

Our primary concern with properly identifying and placing sharps waste or other mailable hazardous materials in the mailstream is the safety of our employees, the mailstream, and the public who may come in contact with these mailpieces. This approval is granted with the understanding that the Postal Service may rescind this authorization if it is subsequently determined that a safety concern or negative operational

475 L'Enfant Plaza SW Room 4446  
 Washington DC 20260-5015  
[www.pe.usps.com](http://www.pe.usps.com)



- 2 -

impact is disclosed; or if it is discovered that your mailing practices violate USPS regulations or the terms of this authorization. Be advised that full responsibility rests with the mailer for any violation of Title 18, United States Code, and section 1716, *Injurious Articles as Nonmailable*, which may result from placing nonmailable items in the mail.

The Postal Service appreciates this opportunity to accommodate your business needs through the approval of this authorization. Should you have any questions, please email Product Classification at [ProductClassification@usps.gov](mailto:ProductClassification@usps.gov).

Sincerely,

Dale E. Kennedy  
Manager, Product Classification

CERTIFIED MAIL – emailed in lieu of certified

cc: Manager, Pricing & Classification Service Center

PC: J Anderson #112553

## **Appendix B. California State Board of Pharmacy Compliance Certification**



**California State Board of Pharmacy**  
2720 Gateway Oaks Drive, Suite 100  
Sacramento, CA 95833  
Phone: (916) 518-3100 Fax: (916) 574-8618  
[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

Business, Consumer Services and Housing Agency  
Department of Consumer Affairs  
Gavin Newsom, Governor



VIA EMAIL

September 23, 2021

Sarah Hanssen  
Vice President, Sales & Marketing  
UltiMed, Inc.  
350 Highway 7  
Excelsior, MN 55331

Dear Ms. Hanssen,

Pursuant to Section 42032(b) of the Public Resources Code, this letter constitutes the California Board of Pharmacy's (Board) response to the updated UltiMed plan for sharps you submitted to the Board on September 20, 2021 entitled "UltiMed Sharps Stewardship Plan" (Plan) that has the name, "Final UltiMed Stewardship Plan v.1.2 – 09162021" in the header of the document. We believe that your Plan complies with pharmacy law of California.

Our review was based solely on California pharmacy law. In evaluating your Plan for compliance with pharmacy law, the Board relied upon the facts and details contained in the Plan. Please note that any different or additional facts in the design or operation of your Plan could result in a different conclusion.

Please note: For certain facilities or pharmacies overseen by other agencies or boards, there could be additional requirements for those types of facilities. As such, the Board's determination of compliance should not be interpreted as a determination of full compliance with all legal provisions.

Sincerely,

Lyle Matthews, Pharm.D., MAM  
Inspector  
California State Board of Pharmacy

Cc: Jason Smyth – CalRecycle

## **Appendix C. California Department of Public Health Compliance Certification**



TOMÁS J. ARAGÓN, M.D., Dr.P.H.  
Director and State Public Health Officer

State of California—Health and Human Services Agency  
**California Department of Public Health**



GAVIN NEWSOM  
Governor

October 1, 2021

Mr. Jim Erickson  
President and CEO  
UltiMed, Inc.  
350 Highway 7  
Excelsior, MN 55331

**RE: Product Stewardship Plan for Covered Sharps from Households;  
DETERMINATION OF COMPLIANCE**

Dear Mr. Erickson:

The California Department of Public Health, Medical Waste Management Program (Department) has reviewed the UltiMed Sharps Stewardship Plan (Plan) to become an approved program operator through California's Pharmaceutical and Sharps Waste Stewardship Program (established by Senate Bill 212) to operate sharps takeback programs in cities and counties in California.

The Department determined that the revised Plan submitted on September 27, 2021 is compliant with the Medical Waste Management Act, California Health and Safety Code Section 117600 *et seq.* (MWMA).

If you have any questions or need further assistance regarding the Department's review, please feel free to contact me directly by phone at 916-210-8533 or via email at [Thomas.Horner@cdph.ca.gov](mailto:Thomas.Horner@cdph.ca.gov).

Sincerely,



Digitally signed by Thomas  
Horner  
Date: 2021.10.01 16:55:17  
-07'00'

Thomas Horner  
Senior Environmental Scientist  
Chief, Medical Waste Management Program

Medical Waste Management Program, MS 7405, IMS K-2 • P.O. Box 997377  
Sacramento, CA 95899-7377 • (916) 449-5671  
[www.cdph.ca.gov/medicalwaste](http://www.cdph.ca.gov/medicalwaste)



Mr. Jim Erickson  
October 1, 2021  
Page 2

cc: Sheetal Singh, PhD  
Environmental Program Manager I  
Chief, Emergency, Restoration, and Waste Management Section

Jennifer Li  
Environmental Scientist  
Medical Waste Management Program