

ULTIMED
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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

UltiMed, Inc. is privileged to submit our stewardship plan to the State of California for review and approval. This stewardship plan has been organized, generated, and developed with our highest level of integrity. As such, we affirm that this stewardship plan, including initial program budget, is complete and true to best of our knowledge. We provide the following perjury statement to affirm this declaration.

Perjury Statement and Signature

I, Jim Erickson, President and CEO of UltiMed, Inc., hereby declare, under penalty of perjury, that the information provided in this document is true and correct, to the best of my knowledge.

A handwritten signature in black ink, appearing to be 'JE' with a stylized flourish extending from the top right.

Jim Erickson,
President and CEO
UltiMed, Inc.

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.



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- 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
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- Wes Nelson, Sales & Marketing Manager
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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 mail-back solution with all sharps dispensed in the State of California at no additional charge to the consumer. 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 end user patients. 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,



Jim Erickson
President & CEO
UltiMed, Inc.

Leader in Sharps Stewardship

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 for managing our mail-back program for sharps devices used for in-home injections. 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 and mail-back processes in the State.

Section 2. Contact Information

Selecting a qualified and experienced professional to spearhead our stewardship program is key to plan 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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Program Operator: UltiMed, Inc.

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Section 3. Covered Entities

UltiMed uniquely designates itself as the sole and only covered entity. Because UltiMed is positioned as a leader in supplying a one-stop solution for dispensing and disposing of used pen needles and syringes, we have the uncommon capability to act as our own covered entity without engaging third parties. Our UltiGuard Safe Pack solution provides pharmacies and end users an all-in-one solution for dispensing pen needles or syringes in one single, self-contained, puncture-resistant, and Food and Drug Administration (FDA)-cleared sharps container. Currently, UltiMed is the only sharps manufacturer that sells sharps with a container for the safe disposal of used sharps, at no additional cost to consumers.

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.

350 Highway 7, Suite 100

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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 solutions. These fully-compliant solutions 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

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 stewardship 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 stewardship education.
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:** Although UltiMed does not anticipate having any grant or loan expenses, sponsorships may be used when appropriate for market outreach. Sponsorships to organizations, such as the American Diabetes Association (ADA) or the American Association of Diabetes Educators (AADE) are anticipated.
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 stewardship activities.

UltiMed is operating the stewardship program on its own and 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

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
Recommended Funding Level (CCR 18973.6)	\$175,802	\$152,750	\$402,363	\$436,467	\$492,937
Stewardship Program Costs (CCR 18973.6)					
Stewardship Capital Costs (CCR 18973.6)					
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 stewardship education.</i> <i>Product setup costs include items related to developing the mail-back product line (i.e., packaging, labeling, education, Website, and inventory).</i>					
Stewardship Recurring Costs (CCR 18973.6)					
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 outreach program (such as flyers, education, informationals, and diagrams).</i>					
Grants, Loans, Sponsorships	5,000	5,750	6,613	7,604	8,745
Independent Financial Audit Expense (CCR 18973.6)	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>					
Departmental Administrative Fee (PRC 42034)	0	0	75,000	60,000	60,000
<i>CalRecycle fees and/or other departmental administrative fees.</i>					
Total	55,000	152,750	402,363	436,467	492,937
Total Annual Costs	\$175,802	\$152,750	\$402,363	\$436,467	\$492,937
Recommended Reserve Level Amount (CCR 18973)	\$87,901	\$76,375	\$201,182	\$218,234	\$246,469
<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 the 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 devices. 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 product 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 consumer-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 medical device container design and executes a proven plan for distributing mail-back materials. Pioneering and engineering an all-in-one container design, our UltiGuard Safe Pack sharps container (see [Figure 1](#) on page [20](#)) allows end users 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 of the 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 plans address all the safety concerns associated with consumed sharps devices, while

delivering end user, pharmaceutical, and physician-used 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, and self-enclosing plastic shell with two main compartments: A dispensing compartment for accessing new sharps devices and a sealed disposal compartment for disposing used sharps devices. Each container comprises 100 sharps with enough room in its disposal compartment to house used sharps. From one single container (the UltiGuard Safe Pack container), ultimate end users conveniently follow three simple steps for using the product after initially receiving it and opening packaging:

7. Dispense new, unused, and sterile sharps devices from the UltiGuard Safe Pack container whenever needed,
8. Dispose of the used sharps devices in the UltiGuard Safe Pack container, and, 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 end users never have to dispose of used needles through any other means. Our product reinforces proper consumer behavior for disposing used needles directly in the UltiGuard Safe Pack container because it is easy and convenient to use.

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

UltiGuard Safe Pack is easy to use with little opportunity for end user confusion. Everything needed to dispense and dispose of sharps devices is housed in one container. Also, after the unit's supply is exhausted or no longer needed, everything needed to return the entire device, including return forms, prepaid postage labels, return shipping box, and materials, are provided (in English and Spanish) in the original shipping box. UltiGuard Safe Pack provides a simple and convenient process for returning the UltiGuard Safe Pack container to UltiMed's wastes disposal representative.

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

7.1.1. UltiMed End User 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 mail-back plan. Our process for distributing mail-back materials is built into our manufacturing process at our De Smet, SD manufacturing facility. First, each container is packed with 100 new sharps devices, 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 end user convenience, we, literally, provide everything our end users need to return the sharps container—from the prepaid and pre-addressed mail-back label and mail-back box (see [Figure 2](#)) to the plastic re-closable disposal bag for the container and shipping tape. To offset and deter end user reluctance, all materials are included in our off-the-shelf, branded package. Our mail-back materials include 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 container using our mail-back process. To further ensure inclusivity, all our brochures are additionally translated in Spanish as well. UltiMed's mail-back materials, combined with each box of sharps, is sold at the

point of sale, and the one set of mail-back materials included in each package is sufficient enough to accommodate the volume of sharps purchased.



Figure 3. UltiGuard Safe Pack Mail-back Brochures

7.1.2. Consumer-provided 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 on disposing of used sharps devices,
- Communicating the importance of adhering to local and federal laws relative to the safe disposal sharps, and
- Stating, in broad terms, the consequences for disregarding local and federal mandates for disposing of used sharps.

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

- Product instructions
- Unpacking/Mail-back instructional brochure

- A prepaid and pre-addressed mail-back label
- A prepaid mail-back box

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 end users and pharmacists, who assist ultimate end 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 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 more ably 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 sharps 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 end user at the point of sale inside product packaging. Instructions and additional information with regards to proper disposal of sharps devices references our [Safe Needle Disposal](#) website.


7.1.3. Sharps Waste Container Labelling

Acting as a responsive provider, UltiMed demonstrates availability to our end users by providing means for them to easily contact us through our dedicated 1-844-8SHARPS (8-844-877-2777) toll-free customer service telephone number. Our website address, www.disposemyneedles.com (to be rolled out by July 2022), along with our toll-free number for contacting us, are to be printed on the outer packaging of all related products. Our contact information further details the days and hours of our operations so that our end users can plan accordingly should they need to contact us. Instructional booklets adhered to our containers, list our website address and toll-free telephone number as well. Our company strives to communicate this important contact information on every piece of our product publications and packaging.

7.1.4. Prepaid Mail-back Postage

Maximizing the probability of the return of used sharps is paramount to the success of our disposable solution for all used sharps. Coordinating mail-back and prepaid postage with the US Postal Service (USPS) in advance provides end 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 solutions increases the probability of the mailing back of our containers.

Product Classification

 UNITED STATES POSTAL SERVICE

February 1, 2021

Jeffery Miglino
 PureWay Compliance, Inc.
 16225 Park Ten Place Ste 830
 Houston, TX 77054-5155
jmiglino@pureway.com

Re: Sharps Container Authorization

Dear Mr. Miglino:

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, 7/25/20
USPS-037S20	MBSYR1001	Sharps	1x Insulin Syringe Shipper	20-038.2, 7/29/20

Disposal Site Locations for PureWay Compliance Inc.:

- 17340 Bell N Dr. Schertz TX 78154 (Medsharps)
- 6602 W 9th Av Gary, IN 46406 (HWM)
- 3200 Hawkins Point Rd Baltimore, MD 21226 (Curtis Bay)
- 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

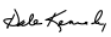
475 L Street Plaza SW Room 4446
 Washington DC 20580-5015
www.usps.com

- 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 Abnormal, 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.

Sincerely,


 Dale E. Kennedy
 Manager, Product Classification

CERTIFIED MAIL – emailed in lieu of certified

cc: Manager, Pricing & Classification Service Center

PC: J Anderson #112553

475 L Street Plaza SW Room 4446
 Washington DC 20580-5015
www.usps.com

Figure 4. Prepaid USPS Coordination and Approval Letter

7.2. Collection, Transportation, and Disposal System Records

Our records management process is designed for accountability and transparency. It is our intent to ensure that records are maintained and managed in an audit ready fashion. UltiMed plans to generate collection, transportation, and disposal records according to our current sharps mail-back programs. Records include:

- Collection manifests (which are provided in a PDF file format)
- Mailer origination (the US Postal Service is used)
- Final disposal documentation

All records and associated information are collected, stored, and managed by UltiMed's sharps disposal service provider and stewardship operator.

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 are sent to the Medsharps disposal location in Schertz, TX. 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
Provider Name	United States Postal Service (USPS)	PureWay Compliance, Inc.
Provider Mailing and Physical Address	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
Provider Mailing and Physical Address	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
Provider Mailing and Physical Address	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 end 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 [27](#).

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 end 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 stewardship operator and participant, 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 [27](#).


7.5. Metrics for Measuring Home-generated Sharps Waste Containers, Distributed Materials, and Returned Sharps Waste

UltiMed and its sharps waste service provider, PureWay, tracks 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 distributors (and pharmacies). PureWay uses its Order Tracking System (OTS), a desktop-based printing system, allowing users to use barcoded compliance tracking manifests for each container they receive to return used sharps. Along with UltiMed's standard product materials, each sharps container packaging is equipped with a tracking manifest and two different labels (a USPS prepaid and pre-addressed return shipping label and a barcode sticker with a lot number). The manifest (see [Figure 5](#) on page [29](#)) and USPS labels are tagged with unique identifiers for distributor and tracking purposes so that when they are returned, we can track to which distributor the item is sold and to which ultimate end user the container is provided.

From the information gathered during the aforementioned process, UltiMed will collect data to create measurable metrics. Specifically, we will track units of compliant product:

- Distributed into the State of California
- Returned to USPS
- Returned to a disposal location for destruction

With this information, UltiMed will calculate a compliance rate defined as **Compliance Rate** (or units of compliant product returned through the USPS, divided by units distributed into the State of California).



ULTIMED
 INCORPORATED



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 _____

4. STATE / ESTADO _____

7. SIGNATURE / FIRMA _____

3. CITY / CIUDAD _____

5. ZIP / CÓDIGO POSTAL _____

6. PHONE / TELÉFONO _____

8. DATE SHIPPED / FECHA DEL ENVÍO _____

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

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 or contact us at 1-844-8SHARPS (1-844-874-2777).
 Si necesita asistencia, visite nuestro sitio web (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

Figure 5. UltiMed Mail-back Compliance Tracking Manifest Sample

7.6. Metrics for Measuring Home-generated Sharps Waste Collection

See [Alternate Sharps Waste Collection Methods](#) on page 27 for more information.

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

See [Alternate Sharps Waste Collection Methods](#) on page 27 for more information.

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 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 stewardship operator and participant, 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.

Section 8. Local Agency Reimbursement

Upon request and in coordination with other sharps Stewardship Program Operators, UltiMed reimburses local agencies for transportation and disposal costs related to home-generated sharps waste collected at local household hazardous waste facilities. A local agency may request reimbursement by registering with coordinating Program Operators or UltiMed. To register, the local agency provides:

- The facility name,
- The name of the point of contact, and
- A completed U.S. Department of the Treasury Internal Revenue Service Form W-9 for the facility to receive reimbursement.

UltiMed, or any other sharps Stewardship Program Operator, then verifies that the household hazardous waste facility is listed on the California Department of Public Health and California Department of Toxic Substances Control websites.

After registering, the local agency may submit a request for reimbursement to coordinating Program Operators or UltiMed. The request:

- Is limited to the actual costs of transportation and disposal incurred in 270 days or more after plan approval.
- Includes an invoice for the costs to be reimbursed.
- Is submitted with a declaration under penalty of perjury that the local agency has not knowingly requested reimbursement for expenses prohibited by the law, including for sharps waste from a needle exchange program or medical waste generator.
- Requires the local agency to report on the total amount, by weight, of home-generated sharps waste disposed.

UltiMed, or any other sharps Stewardship Program Operator, responds to local agency requests within 14 days and issues payment within 45 days of receipt of the local agency's invoice. Reimbursements from UltiMed is issued with a statement that the local agency attests under penalty of perjury that by settling the payment, they are eligible for reimbursement and all reimbursed expenses are allowed under PRC 42032.2(d)(1)(F)(ii) and 14 CCR 18973.3(g).

UltiMed will request from the local agency any information stipulated under 14 CCR 18973.5(p) to be included in the annual report.

Section 9. Ordinance Repeals

Ordinance repeals are not applicable to UltiMed's stewardship program initiatives. Our stewardship plan (and products introduced under our plan) provide a mail-back solution with every product distributed. Any local stewardship program in existence and/or repealed at any time has minimal impact on the mail-back products covered under this stewardship plan.

Section 10. Education and Outreach

10.1. Activities to Promote Awareness and Maximize User Participation

According to the Pew Research Organization, most Americans retrieve information through four main sources: Smartphone (86%), television (40%), radio (16%), and print material (10%). With these statistics as a basis and under the leadership of our stewardship program operator, UltiMed intends to promote and increase user participation in our stewardship program through these mediums, especially online and smartphone messaging platforms, including the use of QR codes to access online information. Promoting awareness and education, we plan to create and provide customary materials to multiple levels of distribution channels, including wholesalers, retailers, pharmacies, consumers, and other stakeholders.

UltiMed's education and outreach tactics in the sharps disposal ecosystem are focused on:

- Increasing awareness,
- Adopting desired practices, and
- Implementing effective communication.

The program uses marketing-based metrics to assess the effectiveness of outreach efforts. Marketing tactics are created to support the program's efforts around market development, leading to increased safe sharps disposal. It is our assumption that outreach success will contribute to operational success. All marketing tactics are directly related to support the effort to provide information to both target audiences identified in the stewardship plan and the legislation, to encourage the behavior change necessary to meeting the program's goals. For example, as the program informs more pharmacists about the new SB-212 all-in-one fully compliant solution, we expect that more sharps will be diverted from landfills.

10.2. Material Localization

Identifying with primary ethnic groups within the State of California (English and Spanish speaking Californians), UltiMed intends to provide marketing materials, flyers, brochures, mail-back materials, and so forth initially in English and Spanish. UltiMed's dedicated Customer Service phone number 1-844-8SHARPS (1-844-877-2777) will be available to further assist, advantageously, all languages, including Asian languages, such as Chinese, Tagalog, and Vietnamese.

See [Website and Website Localization](#) on page [34](#) for more information.

10.3. Website and Website Localization

Our ability to standup a user-friendly Website that is accessible to California's 40 million citizens of diverse ethnicities is important to developing multi-level communication channels for our end users, physicians, pharmacies, and distributors. California, according to the U.S. Bureau of Statistics, is home to primarily English and Spanish speaking communities, with Asian being the third highest population in the state. Of the 25% of Hispanic communities, 86% of them speak Spanish. Also tabulated by the U.S. Bureau of Statistics is California's approximate 7 percent disabled populations, plus its 1.5 million veterans. As such, UltiMed intends to provide Website information initially in English and Spanish, complying with Section 7295 of the U.S. Government Code, and we intend to provide an Americans with Disabilities Act (ADA)-accessible Website to ensure total coverage to end users with disabilities. Furthermore, marketing materials, mail-back materials, flyers, brochures, and so forth will be translated in English and Spanish and be ADA-compliant, where possible.

10.4. Toll-free Telephone Number and Customer Support

Easy accessibility to our teams for all our constituency is our intent and goal. UltiMed has proposed an all-in-one sharps container solution that dispenses and disposes sharps in a returnable container, and therefore, requesting containers is typically not needed. However, UltiMed does provide a toll-free telephone number to all users and participants, professional and non-professional. Such telephone access will field questions and concerns and accommodate veterans and those that are disabled and hearing impaired. Access to a human representative will be made available to all callers upon request. Lastly, constituents will have the option of hearing information in English or Spanish and request to speak with a Spanish speaking representative. Live telephone support will provide full translation services, as described in [Material Localization](#) on page [33](#) and Website and Website Localization on page [34](#). With these options in place UltiMed will achieve its accessibility goal.

10.5. Education and Outreach Metrics

Metrics will be established to evaluate the performance of the education provided to our ultimate end 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 end 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 compliant product distributed into the State of California
- Track units of compliant product returned to USPS
- Track units of compliant product returned to a disposal location for destruction
- Track pharmacy locations that stock the product
- Track pharmacy re-stocking activities
- Assess estimated pharmacy penetration rates
- 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 stewardship 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 end users alike.

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. UltiMed's program operator will make all efforts to ensure that only those products under our program 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.

Section 11. Coordination Efforts

Constant communication, coordination, and collaboration are keys to promoting relative business and end user strategies, initiatives, and plans coexisting among multiple program operators in effort to align with CalRecycle initiatives. Under the leadership of our stewardship program point of contact, where appropriate, UltiMed intends to engage and align ourselves with CalRecycle initiatives. Such coordination could conceptually be offered through coordinated and strategic engagements, dialogue, and validated market insertions, as applicable. Other coordinated efforts may be included; however, our intention is to maintain alignment with current CalRecycle initiatives, submitting our annual report consistently and hosting educational programs, if needed, internally and externally to our organizations. UltiMed's regular and concerted collaboration and communication effort is dependent on business stakeholders across the board. Our goal is to be current and in sync with CalRecycle, the primary authority, as much as possible, and mimic and propagate CalRecycle's stewardship program initiatives.

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

No grants, loans, sponsorships, reimbursements, or other incentives are anticipated at this time under our stewardship program.

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 operate in the best value of our product offerings. UltiMed strives to add value while acting in the best interest of the company and our end users.

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

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



- 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.

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

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.

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



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