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December 20, 2004

***VIA FEDERAL EXPRESS***

Mr. Ryan Posten  
Exemptions Officer  
Hazardous Materials Division  
Federal Motor Carrier Safety Administration  
U.S. Department of Transportation  
400 7th Street, S.W., PL-401  
Washington DC 20590-0001

Re: Medical Systems, Inc., 1601 Sublette Avenue, St. Louis, MO 63110  
Request for Emergency Exemption and/or Party Status to DOT-E 13556

Dear Mr. Posten:

The undersigned represents Medical Systems, Inc. ("MSI"). MSI would like to request an emergency exemption under 49 CFR 107.11 based on the potential economic impact of the regulations on our operations and our health care customers. MSI requests an exemption from the "leak proof" requirement under 49 CFR 173.24 to allow sharps containers to be transported in carts during the course of normal transport. Exemption has previously been granted to BioSystems, Inc. on June 18, 2004.

The following information outlines MSI's request:

MSI has been providing services to hospitals in the St. Louis metropolitan area for the past 14 years. The sharps management program is a simple exchange process facilitated by a very low cost and safe sharps container program. Empty sharps containers are delivered to the hospital in a secured transportation cart. MSI technicians use the carts to collect and replace sharps containers at their point of use (i.e., patient rooms) within the hospital. After the service is completed, the carts are then brought down to the loading docks where technicians document and prepare the carts for transport. The carts are designed to secure the sharps containers for transport. Loaded carts are placed in the MSI transport trucks. The carts are secured to the truck using tie down straps. The trucks transport the loaded carts to the MSI treatment facility for processing. (See photographs attached.)

JCDOCS 20716v1

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The sharps management program has proven itself as the preferred method for sharps management. The program eliminates multiple costs to the customer including purchasing, warehousing and maintaining inventory of containers, and time associated with changing containers by their own staff. Additionally, the program reduces the risk of needle stick to the hospital employees from overfilled containers. Over the past 14 years, MSI sharps program has eliminated approximately 56,000 needle stick injuries associated with sharps containers. Lastly, the program increases sharps management accountability within each facility and provides for the safe and secure transport and disposal of sharps.

MSI's sharps containers meet the DOT regulatory requirements for puncture resistance and weight limit. They have been registered and have received clearance for marketing under the FDA Medical Device Act 510k(k) process. The containers are appropriately marked for transport pursuant to the DOT and OSHA regulations under 29 CFR 1910.1030. The containers are not intended for liquids; however are leak proof on all sides and at the bottom. As part of our service to our customers, we make every effort to educate them that we cannot accept free or bulk liquids in these containers. Customers do place stoppered tubes, pipettes or canisters containing fluids in these sharps containers because they believe they have the potential of becoming a sharp. The use of carts ensures the containers are maintained in an upright position and thus eliminates the possibility of leakage during transport if these materials were to break.

The current regulations address the general packaging requirements under 49 CFR 173.24 and speak to the regulated medical waste general requirements under 173.197 but do not speak to this specific case. We understand that under 49 CFR 173.24(f) the closure is required to be leak proof for conditions "normally incident to transport". We believe sharps containers secured within transportation carts are leak proof during normal transport.

MSI has been transporting containers utilizing secured carts for 14 years, and in that time we have seen no evidence of containers having a release or causing injury while secured in carts under conditions normally incident to transport. The containers are loaded and secured onto the carts and the carts are secured on the trucks thereby eliminating the potential to tip over and spill. Our drivers are trained and are experts in spill response and in the handling of medical wastes. We are totally dedicated to our customers with regard to the collection, handling and treatment of hazardous materials. Further, our trucks are equipped with spill response equipment.

For your convenience, attached as exhibits A through C are the following:

- A. DOT-E 13556;

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- B. Photographs of cart with containers; and
- C. Specifications for cart.

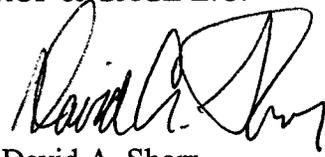
We believe that the above-described method of transport is a safe, efficient and effective way to transport sharps containers.

Thank you for your consideration of our request for exemption.

Very truly yours,

LATHROP & GAGE L.C.

By:



David A. Shorr

DAS/jf  
Enclosures  
cc: Regis Hillow

## **EXHIBIT B**

Photographs of Cart  
with Containers





# **EXHIBIT C**

## Specifications for Cart



Item # \_\_\_\_\_

Job \_\_\_\_\_



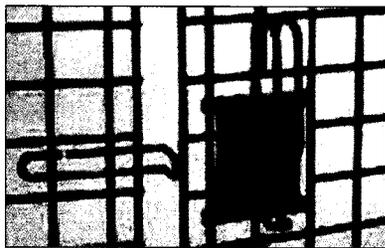
Security Units

## SECURITY UNITS Features:

- **Safe Storage:** Protects valuable materials and sensitive items from loss or pilferage.
- **Microban® Antimicrobial Product Protection\*:** Metroseal 3 models and MetroMax Q shelf mats feature Microban Antimicrobial Product Protection, designed to stay "cleaner between cleanings."
- **Ready View of Contents:** Heavy-gauge open wire construction keeps the entire contents of the truck visible at all times, making it easy to check inventory.
- **Adjustable, Optional Intermediate Shelves:** Patented, easily adjustable shelf designs — Super Adjustable Super Erecta, MetroMax Q, and qwikSLOT — allow flexibility to meet changing needs. Can be positioned in 1" (25 mm) increments along the entire height of post.
- **Patented, Ergonomic, 1/4-Turn Door Handle:** Makes opening and closing the unit easier than conventional security unit designs.
- **Double Door:** Each door opens 270 degrees and can be secured along the sides of the unit.
- **Time Saving Assembly:** Metro security units assemble quickly — right out of the box.
- **Shipped Knocked-Down:** Saves on freight costs. Easily assembled.

### Choose from Stationary or Mobile Standard and Heavy-Duty Configurations:

- **Safe Transportation:** Mobile, security trucks provide the advantage of quick, protective transportation.
- **Easy Cleaning of Storage Areas:** Mobile units move easily from walls to allow thorough cleaning of floors and walls.
- **Mobile Units:** Available in Standard and Heavy-Duty models. Heavy-Duty units offer increased rigidity and durability for applications such as crossing thresholds.
- **Stationary Units:** Posts have leveling feet to compensate for uneven surfaces.



handle (open position)

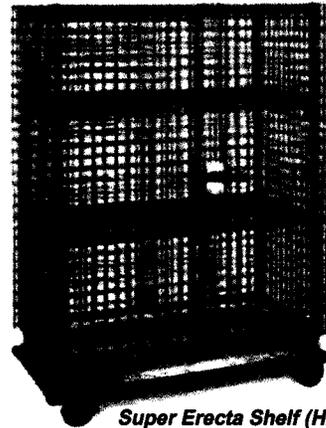


handle (closed position)

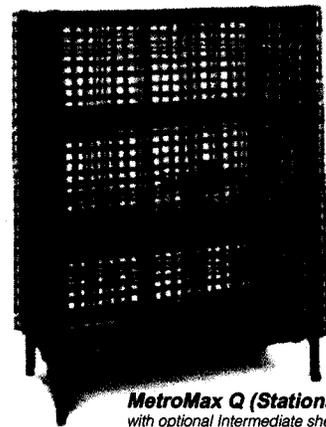
\*MICROBAN® and the MICROBAN® symbol are registered trademarks of the Microban Products Company, Huntersville, NC.



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**Super Erecta Shelf (HD Mobile)**  
with optional Super Adjustable/  
Super Erecta® Intermediate shelves



**MetroMax Q (Stationary)**  
with optional Intermediate shelves



**qwikSLOT (Mobile)**  
with optional Intermediate shelves



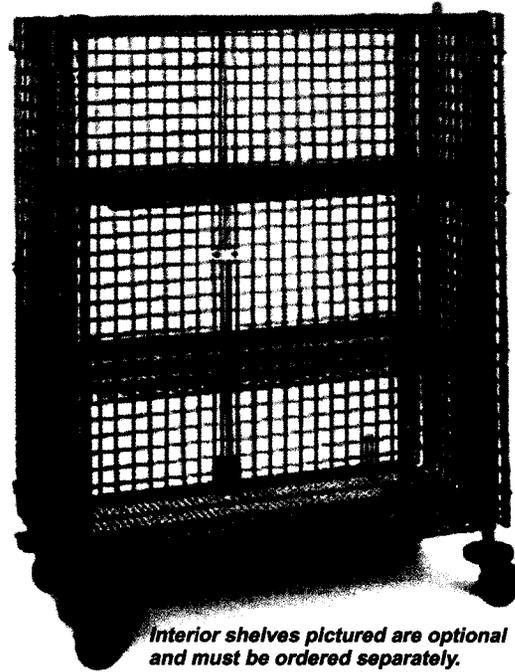
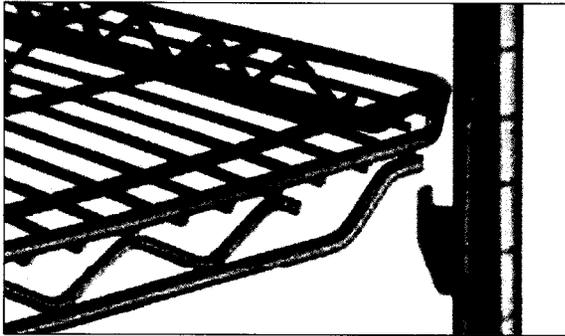
**EMERSON**  
Storage Solutions

14.01

# SECURITY UNITS

## METRO® qwikSLOT™ SECURITY UNITS

- **Add/Remove a Shelf Feature:** Allows the unit to be quickly adapted to fit your changing storage needs.
- **Shelves can easily be adjusted in seconds.**



*Interior shelves pictured are optional and must be ordered separately.*

### Specifications qwikSLOT Stationary Security

| Cat. No.<br>Chrome | Width                          |      | Length                         |      | Height                           |      | Approx. Pkd. Wt. |      |
|--------------------|--------------------------------|------|--------------------------------|------|----------------------------------|------|------------------|------|
|                    | (in.)                          | (mm) | (in.)                          | (mm) | (in.)                            | (mm) | (lbs.)           | (kg) |
| SEC53CQ            | 27 <sup>1</sup> / <sub>4</sub> | 705  | 38 <sup>1</sup> / <sub>2</sub> | 980  | 66 <sup>13</sup> / <sub>16</sub> | 1695 | 154              | 70   |
| SEC55CQ            | 27 <sup>1</sup> / <sub>4</sub> | 705  | 50 <sup>1</sup> / <sub>2</sub> | 1283 | 66 <sup>13</sup> / <sub>16</sub> | 1695 | 174              | 79   |
| SEC56CQ            | 27 <sup>1</sup> / <sub>4</sub> | 705  | 62 <sup>1</sup> / <sub>2</sub> | 1587 | 66 <sup>13</sup> / <sub>16</sub> | 1695 | 195              | 89   |

### qwikSLOT Mobile Security

**Standard-Duty Stem Caster Models:** feature 5" (127mm) swivel casters. Please note model numbers for specific caster types.

| Cat. No.<br>Chrome | Caster Type  | Width                          |      | Length                         |      | Height                         |      | Approx. Pkd. Wt. |      |
|--------------------|--------------|--------------------------------|------|--------------------------------|------|--------------------------------|------|------------------|------|
|                    |              | (in.)                          | (mm) | (in.)                          | (mm) | (in.)                          | (mm) | (lbs.)           | (kg) |
| SEC53DCQ           | (4) 5MP      | 27 <sup>1</sup> / <sub>4</sub> | 692  | 40 <sup>3</sup> / <sub>4</sub> | 1035 | 68 <sup>1</sup> / <sub>2</sub> | 1740 | 162              | 74   |
| SEC55DCQ           | (4) 5MP      | 27 <sup>1</sup> / <sub>4</sub> | 692  | 52 <sup>3</sup> / <sub>4</sub> | 1340 | 68 <sup>1</sup> / <sub>2</sub> | 1740 | 182              | 83   |
| SEC56DCQ           | (4) 5MP      | 27 <sup>1</sup> / <sub>4</sub> | 692  | 65                             | 1651 | 68 <sup>1</sup> / <sub>2</sub> | 1740 | 203              | 92   |
| SEC53ECQ           | (2) 5MP/5MPB | 27 <sup>1</sup> / <sub>4</sub> | 692  | 40 <sup>3</sup> / <sub>4</sub> | 1035 | 68 <sup>1</sup> / <sub>2</sub> | 1740 | 162              | 74   |
| SEC55ECQ           | (2) 5MP/5MPB | 27 <sup>1</sup> / <sub>4</sub> | 692  | 52 <sup>3</sup> / <sub>4</sub> | 1340 | 68 <sup>1</sup> / <sub>2</sub> | 1740 | 182              | 83   |
| SEC56ECQ           | (2) 5MP/5MPB | 27 <sup>1</sup> / <sub>4</sub> | 692  | 65                             | 1651 | 68 <sup>1</sup> / <sub>2</sub> | 1740 | 203              | 92   |

Casters: 5MP and 5MPB (with locking brake) feature a polyurethane tread. 5PC and 5PCB (with locking brake) casters feature a polymer horn and resist rusting. They are recommended for high moisture environments.

**CAUTION:** Large casters can create a tipping hazard. On 18" (457mm) security units, do not use casters larger than 5" (127mm) in diameter.

**Heavy-Duty Models:** feature aluminum dollies with wraparound bumpers and 5" (127mm) diameter casters.

| Cat. No.<br>Chrome | Caster Type  | Width                           |      | Length                         |      | Height                         |      | Approx. Pkd. Wt. |      |
|--------------------|--------------|---------------------------------|------|--------------------------------|------|--------------------------------|------|------------------|------|
|                    |              | (in.)                           | (mm) | (in.)                          | (mm) | (in.)                          | (mm) | (lbs.)           | (kg) |
| SEC53LCQ           | (2) 5BP/5BPB | 28 <sup>1</sup> / <sub>16</sub> | 713  | 38 <sup>1</sup> / <sub>2</sub> | 980  | 68 <sup>1</sup> / <sub>2</sub> | 1740 | 187              | 85   |
| SEC55LCQ           | (2) 5BP/5BPB | 28 <sup>1</sup> / <sub>16</sub> | 713  | 50 <sup>1</sup> / <sub>2</sub> | 1283 | 68 <sup>1</sup> / <sub>2</sub> | 1740 | 210              | 95   |
| SEC56LCQ           | (2) 5BP/5BPB | 28 <sup>1</sup> / <sub>16</sub> | 713  | 63 <sup>1</sup> / <sub>8</sub> | 1600 | 68 <sup>1</sup> / <sub>2</sub> | 1740 | 235              | 107  |

### Intermediate Shelves for Super Erecta Shelf Security Units

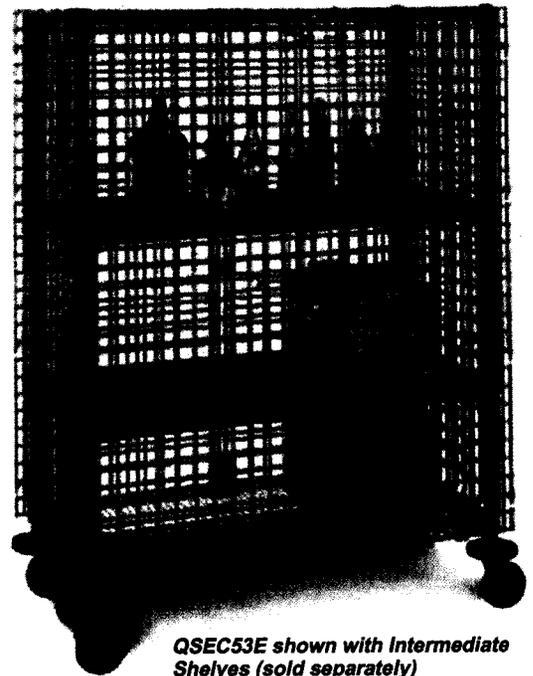
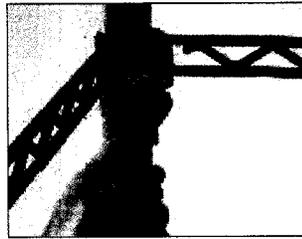
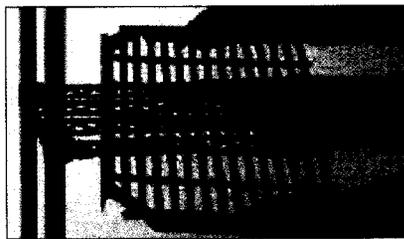
| Cat. No.<br>Chrome | Width |      | Length |      | Approx. Pkd. Wt.               |      |
|--------------------|-------|------|--------|------|--------------------------------|------|
|                    | (in.) | (mm) | (in.)  | (mm) | (lbs.)                         | (kg) |
| 1836QBR*           | 18    | 457  | 36     | 914  | 8 <sup>1</sup> / <sub>2</sub>  | 3.8  |
| 1848QBR*           | 18    | 457  | 48     | 1219 | 11 <sup>1</sup> / <sub>4</sub> | 5.0  |
| 2436QBR*           | 24    | 610  | 36     | 914  | 13                             | 6.0  |
| 2448QBR*           | 24    | 610  | 48     | 1219 | 16                             | 7.0  |
| 2460QBR            | 24    | 610  | 60     | 1524 | 21                             | 9.5  |

\*Chrome qwikSLOT shelves available in sizes 18x36, 18x48, 24x36, and 24x48 (457x914, 457x1219, 610x914, 610x1219, and 610x1524).

\*\*Drop Mat qwikSLOT shelves with 1" (25mm) ledge also available in sizes 24x36, 24x48 (610x914, 610x1219).

# MetroMax Q® SECURITY UNITS

- **Microban® Product Protection:** Polymer mats on intermediate shelves feature built-in Microban antimicrobial product protection, which inhibits the growth of bacteria, mold, mildew, and fungi that cause odors, stains, and product degradation.
- **Cleanable:** Removable polymer mats can be placed in the dishwasher or sink to make cleaning easy.
- **Corrosion Resistant:** Gray epoxy finish is perfect for both dry and high-moisture environments.



**QSEC53E shown with Intermediate Shelves (sold separately)**

## Specifications

### MetroMax Q Stationary Units 66<sup>13</sup>/<sub>16</sub>" (1696mm) high

| Cat. No. | Width                          |      | Length                         |      | Approx. Pkd. Wt. |      |
|----------|--------------------------------|------|--------------------------------|------|------------------|------|
|          | (in.)                          | (mm) | (in.)                          | (mm) | (lbs.)           | (kg) |
| QSEC53E  | 27 <sup>1</sup> / <sub>4</sub> | 692  | 38 <sup>1</sup> / <sub>2</sub> | 980  | 148              | 67   |
| QSEC55E  | 27 <sup>1</sup> / <sub>4</sub> | 692  | 50 <sup>1</sup> / <sub>2</sub> | 1245 | 147              | 67   |
| QSEC56E  | 27 <sup>1</sup> / <sub>4</sub> | 692  | 62 <sup>1</sup> / <sub>2</sub> | 1587 | 151              | 69   |

### MetroMax Q Stem Caster Mobile Units 68<sup>1</sup>/<sub>2</sub>" (1740mm) high

| Standard with four 5" (127mm) diameter swivel casters* | Corrosion Resistant with four polymer casters (2 with brakes)** | Width                          |      | Length                         |      | Approx. Pkd. Wt. |      |
|--|---|--------------------------------|------|--------------------------------|------|------------------|------|
|  |   | (in.)                          | (mm) | (in.)                          | (mm) | (lbs.)           | (kg) |
| QSEC53DE   | QSEC53VE  | 27 <sup>1</sup> / <sub>4</sub> | 692  | 40 <sup>3</sup> / <sub>4</sub> | 1035 | 166              | 75   |
| QSEC55DE   | QSEC55VE  | 27 <sup>1</sup> / <sub>4</sub> | 692  | 52 <sup>2</sup> / <sub>4</sub> | 1340 | 176              | 80   |
| QSEC56DE   | QSEC56VE  | 27 <sup>1</sup> / <sub>4</sub> | 692  | 65                             | 1651 | 179              | 81   |

\*\*DE" models use four 5MP casters.

\*\*\*VE" models use two 5PCX and two 5PCBX casters.

### MetroMax Q Heavy-Duty Mobile Units 67<sup>1</sup>/<sub>8</sub>" (1724mm) high

Mounted on aluminum dolly with 5" (127mm) plate casters and wraparound bumpers.

| Cat. No. | Caster Type | Width                           |      | Length                         |      | Approx. Pkd. Wt. |      |
|----------|-------------|---------------------------------|------|--------------------------------|------|------------------|------|
|          |             | (in.)                           | (mm) | (in.)                          | (mm) | (lbs.)           | (kg) |
| QSEC53LE | B5P/B5PB    | 28 <sup>1</sup> / <sub>16</sub> | 713  | 38 <sup>1</sup> / <sub>2</sub> | 980  | 181              | 82   |
| QSEC55LE | B5P/B5PB    | 28 <sup>1</sup> / <sub>16</sub> | 713  | 50 <sup>1</sup> / <sub>2</sub> | 1285 | 193              | 88   |
| QSEC56LE | B5P/B5PB    | 28 <sup>1</sup> / <sub>16</sub> | 713  | 63 <sup>1</sup> / <sub>8</sub> | 1600 | 201              | 91   |

### Intermediate Shelves for MetroMax Q

| Cat. No. | For Use With                          | Width |      | Length |      | Approx. Pkd. Wt. |      |
|----------|---------------------------------------|-------|------|--------|------|------------------|------|
|          |                                       | (in.) | (mm) | (in.)  | (mm) | (lbs.)           | (kg) |
| Q2436G2  | QSEC53E, QSEC53DE, QSEC53VE, QSEC53LE | 24    | 610  | 36     | 914  | 12               | 5.5  |
| Q2448G2  | QSEC55E, QSEC55DE, QSEC55VE, QSEC55LE | 24    | 610  | 48     | 1219 | 16               | 7.3  |
| Q2460G2  | QSEC56E, QSEC56DE, QSEC56VE, QSEC56LE | 24    | 610  | 60     | 1524 | 20               | 9.1  |