

## FDA Annual Registration of 2016

**FDA Register facility:** SHANGHAI EMSS MED&TECH CO.,LTD

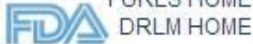
**FDA Registration number:** 3009220813

**FDA Website:** [www.fda.gov](http://www.fda.gov)

**FDA Web link:** <https://www.access.fda.gov/oaa>

**Status:**

  
Device Registration & Listing Module



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| Select                | Reg Number | Reg Status | Status Reason                | Facility Name                  | Address                                                                                                        | Expiration Date |
|-----------------------|------------|------------|------------------------------|--------------------------------|----------------------------------------------------------------------------------------------------------------|-----------------|
| <input type="radio"/> | 3009220813 | Active     | Registration number assigned | SHANGHAI EMSS MED&TECH CO.,LTD | ROOM 303, NO.2, PUJIANG HI-TECH PLAZA, 2388 CH ENHANG ROAD, MINHANG DISTRICT SHANGHAI, SHANGHAI, 201114, CHINA | 2016-12-31      |

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## FDA Registration Listings

| <input type="checkbox"/>            | Listing Number          | Listing Status | Premarket Submission Number/Type | Product Code(s) | Device Name                                                  | Registration Numbers |
|-------------------------------------|-------------------------|----------------|----------------------------------|-----------------|--------------------------------------------------------------|----------------------|
| <input checked="" type="checkbox"/> | <a href="#">D232080</a> | Active         | Exempt                           | NSB             | Patient personal hygiene kit                                 | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D139394</a> | Active         | Exempt                           | FQM             | BANDAGE, ELASTIC                                             | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D208058</a> | Active         | Exempt                           | Gcy             | APPARATUS, SUCTION, SINGLE PATIENT USE, PORTABLE, NONPOWERED | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D208057</a> | Active         | Exempt                           | IMD             | PACK, HOT OR COLD, DISPOSABLE                                | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D208060</a> | Active         | Exempt                           | KGB             | MASK, OXYGEN, NON-REBREATHING                                | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D208061</a> | Active         | Exempt                           | NZD             | Stretcher, patient restraint                                 | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D208063</a> | Active         | Exempt                           | FPO             | STRETCHER, WHEELED                                           | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D146511</a> | Active         | Exempt                           | FOA             | BOARD, CARDIOPULMONARY                                       | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D146512</a> | Active         | Exempt                           | MRI             | ORTHOSIS, TRUNCAL/ORTHOSIS, LIMB                             | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D146302</a> | Active         | Exempt                           | KME             | BEDDING, DISPOSABLE, MEDICAL                                 | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D201134</a> | Active         | Exempt                           | BYP             | MOUTHPIECE, BREATHING                                        | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D135918</a> | Active         | Exempt                           | NOC             | Splint, extremity, non-inflatable, external, non-sterile     | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D135916</a> | Active         | Exempt                           | FPP             | STRETCHER, HAND-CARRIED                                      | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D135917</a> | Active         | Exempt                           | GAX             | TOURNIQUET, NONPNEUMATIC                                     | 3009220813           |
| <input checked="" type="checkbox"/> | <a href="#">D148213</a> | Active         | Exempt                           | HSQ             | BELT, PELVIC, TRACTION                                       | 3009220813           |

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## Stretcher

**(Listing Number: D135916)**

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Device Registration & Listing Module



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|                 |               |
|-----------------|---------------|
| Listing Number  | D135916       |
| Listing Status  | Active        |
| Submission Type | 510(k) exempt |

| Product Code | Product Name            |
|--------------|-------------------------|
| FPP          | STRETCHER, HAND-CARRIED |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                           |
|----------------|---------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Manufacturer, Foreign Exporter, Manufacturer, Remanufacturer, Repackager/Relabeler, Specification Developer |

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| Importer Name         | Address                                                                   |
|-----------------------|---------------------------------------------------------------------------|
| Dentimed Sao Joao LLC | 2213 N Commerce Pkwy Weston, Florida, Weston Florida, 33326 UNITED STATES |

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## Wheel Stretcher

**(Listing Number: D208063)**



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|                 |               |
|-----------------|---------------|
| Listing Number  | D208063       |
| Listing Status  | Active        |
| Submission Type | 510(k) exempt |

| Product Code | Product Name       |
|--------------|--------------------|
| FPO          | STRETCHER, WHEELED |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                     |
|----------------|---------------------|------------------------------|----------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Manufacturer, Foreign Exporter, Manufacturer, Repackager/Relabeler, Reprocessor of Single Use Devices |

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| View Proprietary Names and Labeling                                                                                                                                                              |                                                                           |         |                       |                                                                           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|---------|-----------------------|---------------------------------------------------------------------------|
| <table> <tr> <th>Importer Name</th> <th>Address</th> </tr> <tr> <td>Dentimed Sao Joao LLC</td> <td>2213 N Commerce Pkwy Weston, Florida, Weston Florida, 33326 UNITED STATES</td> </tr> </table> | Importer Name                                                             | Address | Dentimed Sao Joao LLC | 2213 N Commerce Pkwy Weston, Florida, Weston Florida, 33326 UNITED STATES |
| Importer Name                                                                                                                                                                                    | Address                                                                   |         |                       |                                                                           |
| Dentimed Sao Joao LLC                                                                                                                                                                            | 2213 N Commerce Pkwy Weston, Florida, Weston Florida, 33326 UNITED STATES |         |                       |                                                                           |

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## Soft Stretcher 、 Transfer sheet 、 Safety belts

**(Listing Number: D208061)**



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|                 |               |
|-----------------|---------------|
| Listing Number  | D208061       |
| Listing Status  | Active        |
| Submission Type | 510(k) exempt |

| Product Code | Product Name                 |
|--------------|------------------------------|
| NZD          | Stretcher, patient restraint |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                                     |
|----------------|---------------------|------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Manufacturer, Foreign Exporter, Manufacturer, Remanufacturer, Repackager/Relabeler, Reprocessor of Single Use Devices |

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| Importer Name         | Address                                                                   |
|-----------------------|---------------------------------------------------------------------------|
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## Rolled/Flat splint 、Finger splint、Arthrosis splint

**(Listing Number: D135918)**

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### View Selected Listing Details

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Listing Number: D135918  
Listing Status: Active  
Submission Type: 510(k) exempt

| Product Code | Product Name                                             |
|--------------|----------------------------------------------------------|
| NOC          | Splint, extremity, non-inflatable, external, non-sterile |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                           |
|----------------|---------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Manufacturer, Foreign Exporter, Manufacturer, Remanufacturer, Repackager/Relabeler, Specification Developer |

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| Importer Name         | Address                                                                   |
|-----------------------|---------------------------------------------------------------------------|
| DYNAREX CORP.         | 10 Glenshaw St ORANGEBURG New York, 10962 UNITED STATES                   |
| Dentimed Sao Joao LLC | 2213 N Commerce Pkwy Weston, Florida, Weston Florida, 33326 UNITED STATES |

## Traction Splint

**(Listing Number: D148213)**

# DRLM

Device Registration & Listing Module



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|                 |               |
|-----------------|---------------|
| Listing Number  | D148213       |
| Listing Status  | Active        |
| Submission Type | 510(k) exempt |

| Product Code | Product Name           |
|--------------|------------------------|
| HSQ          | BELT, PELVIC, TRACTION |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                           |
|----------------|---------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Manufacturer, Foreign Exporter, Manufacturer, Remanufacturer, Repackager/Relabeler, Specification Developer |

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## Mouthpiece

(Listing Number: D201134)

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Listing Number: D201134

Listing Status: Active

Submission Type: 510(k) exempt

| Product Code | Product Name          |
|--------------|-----------------------|
| BYP          | MOUTHPIECE, BREATHING |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                     |
|----------------|---------------------|------------------------------|----------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Manufacturer, Foreign Exporter, Manufacturer, Repackager/Relabeler, Reprocessor of Single Use Devices |

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| Importer Name                   | Address                                                                         |
|---------------------------------|---------------------------------------------------------------------------------|
| Emergency Medical International | 44W528 Rte. 64 Lily Lake , IL 60151 USA Lily Lake Illinois, 60151 UNITED STATES |

Room 303, No. 2, Pujiang Hi-Tech Plaza, 2388 Chenhang Road, 201114 Shanghai P.R.C  
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## Face mask

(Listing Number: D208060)

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Listing Number

D208060

Listing Status

Active

Submission Type

510(k) exempt

| Product Code | Product Name                  |
|--------------|-------------------------------|
| KGB          | MASK, OXYGEN, NON-REBREATHING |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                                              |
|----------------|---------------------|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Sterilizer, Foreign Exporter, Remanufacturer, Repackager/Relabeler, Reprocessor of Single Use Devices, Specification Developer |

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| Importer Name                   | Address                                                                         |
|---------------------------------|---------------------------------------------------------------------------------|
| Dentimed Sao Joao LLC           | 2213 N Commerce Pkwy Weston, Florida, Weston Florida, 33326 UNITED STATES       |
| Emergency Medical International | 44W528 Rte. 64 Lily Lake , IL 60151 USA Lily Lake Illinois, 60151 UNITED STATES |

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## Thermal blanket 、 Sleeping bag

**(Listing Number: D146302)**

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Listing Number                      D146302  
Listing Status                        Active  
Submission Type                      510(k) exempt

| Product Code | Product Name                 |
|--------------|------------------------------|
| KME          | BEDDING, DISPOSABLE, MEDICAL |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                           |
|----------------|---------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Manufacturer, Foreign Exporter, Manufacturer, Remanufacturer, Repackager/Relabeler, Specification Developer |

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## Head immobilizer、Cervical collar 、Spine board 、Extrication Device

**(Listing Number: D146512)**

**DRLM**

Device Registration & Listing Module



### View Selected Listing Details

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Listing Number D146512  
Listing Status Active  
Submission Type 510(k) exempt

| Product Code | Product Name                     |
|--------------|----------------------------------|
| MRI          | ORTHOSIS, TRUNCAL/ORTHOSIS, LIMB |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                           |
|----------------|---------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Manufacturer, Foreign Exporter, Manufacturer, Remanufacturer, Repackager/Relabeler, Specification Developer |

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|---------------------------------|---------------------------------------------------------------------------------|
| Dentimed Sao Joao LLC           | 2213 N Commerce Pkwy Weston, Florida, Weston Florida, 33326 UNITED STATES       |
| Emergency Medical International | 44W528 Rte. 64 Lily Lake , IL 60151 USA Lily Lake Illinois, 60151 UNITED STATES |

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## CPR board

(Listing Number: D146511)

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Device Registration & Listing Module



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### View Selected Listing Details Get Help ?

|                 |               |
|-----------------|---------------|
| Listing Number  | D146511       |
| Listing Status  | Active        |
| Submission Type | 510(k) exempt |

| Product Code | Product Name           |
|--------------|------------------------|
| FOA          | BOARD, CARDIOPULMONARY |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                           |
|----------------|---------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Manufacturer, Foreign Exporter, Manufacturer, Remanufacturer, Repackager/Relabeler, Specification Developer |

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## Bandage

**(Listing Number: D139394)**

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Listing Number: D139394  
Listing Status: Active  
Submission Type: 510(k) exempt

| Product Code | Product Name     |
|--------------|------------------|
| FQM          | BANDAGE, ELASTIC |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                           |
|----------------|---------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Manufacturer, Foreign Exporter, Manufacturer, Remanufacturer, Repackager/Relabeler, Specification Developer |

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## Tourniquet

**(Listing Number: D135917)**

## DRLM

Device Registration & Listing Module



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### View Selected Listing Details

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Listing Number D135917  
Listing Status Active  
Submission Type 510(k) exempt

| Product Code | Product Name             |
|--------------|--------------------------|
| GAX          | TOURNIQUET, NONPNEUMATIC |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                           |
|----------------|---------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Manufacturer, Foreign Exporter, Manufacturer, Remanufacturer, Repackager/Relabeler, Specification Developer |

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**Hot Pack, Cold Pack**

**(Listing Number: D208057)**

**DRLM**  
Device Registration & Listing Module



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Listing Number D208057  
Listing Status Active  
Submission Type 510(k) exempt

| Product Code | Product Name                  |
|--------------|-------------------------------|
| IMD          | PACK, HOT OR COLD, DISPOSABLE |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                         |
|----------------|---------------------|------------------------------|----------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Foreign Exporter, Repackager/Relabeler, Reprocessor of Single Use Devices, Specification Developer |

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## Manual suction

**(Listing Number: D208058)**

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Device Registration & Listing Module



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### View Selected Listing Details

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Listing Number                      D208058  
Listing Status                        Active  
Submission Type                    510(k) exempt

| Product Code | Product Name                                                 |
|--------------|--------------------------------------------------------------|
| GCY          | APPARATUS, SUCTION, SINGLE PATIENT USE, PORTABLE, NONPOWERED |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                              |
|----------------|---------------------|------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Sterilizer, Foreign Exporter, Repackager/Relabeler, Reprocessor of Single Use Devices, Specification Developer |

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**First aid kit, First aid bag**

**(Listing Number: D232080)**

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Device Registration & Listing Module



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Listing Number D232080  
Listing Status Active  
Submission Type 510(k) exempt

| Product Code | Product Name                 |
|--------------|------------------------------|
| NSB          | Patient personal hygiene kit |

| Registration # | Registration Status | Registration Status Reason   | Activities                                                                                                                        |
|----------------|---------------------|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| 3009220813     | Active              | Registration number assigned | Contract Manufacturer, Foreign Exporter, Manufacturer, Remanufacturer, Reprocessor of Single Use Devices, Specification Developer |

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