

| PRODUCT MASTER DATA SPECIFICATION 0800 | | | | | | | |
|---|------------------------|-----------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| Document Number: SPE003892 | | ECN #: ECN031696 | | Revision (letter): E | | | |
| Master Data / GUDID Data Elements | MDM or SAP Value (Y/N) | LSP Upload Tool Value (Y/N) | Configuration | Configuration | Configuration | Configuration | Configuration |
| | | | 0800 | 010800 | 020800 | ** 030800 | ** 040800 |
| PRODUCT INFORMATION SECTION | | | | | | | |
| Packaging Assembly Number | No | No | N/A | N/A | N/A | ** 0800 Rev E | ** 0800 Rev E |
| Product Shelf Life (Months) | Yes | No | 18 | 18 | 18 | 18 | 18 |
| Maximum Sterilization Dose | No | No | N/A | N/A | N/A | N/A | N/A |
| Company Name | Yes | Yes | Megadyne Medical Products, Inc | Megadyne Medical Products, Inc | Megadyne Medical Products, Inc | Megadyne Medical Products, Inc | Megadyne Medical Products, Inc |
| Single Use Product? | Yes | Yes | No | No | No | No | No |
| Capital Indicator | Yes | No | Yes | Yes | Yes | Yes | Yes |
| Associated Product Code Indicator | Yes | No | No | No | No | No | No |
| Associated Product Code | No | No | N/A | N/A | N/A | N/A | N/A |
| Special Storage Requirement Code / Conditions: | Yes | Yes | N/A | N/A | N/A | N/A | N/A |
| Product SubType | Yes | No | Manufactured Finished Good | Manufactured Finished Good | Manufactured Finished Good | Manufactured Finished Good | Manufactured Finished Good |
| Is this product software? | Yes | No | No | No | No | No | No |
| Is product considered hazardous? | Yes | No | Not Hazardeous | Not Hazardeous | Not Hazardeous | Not Hazardeous | Not Hazardeous |
| Device Part Marking Required? | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Device Part Marking Exemption Rationale (if "No" in Row 26) | Yes | Yes | NA | NA | NA | NA | NA |
| GTIN (Primary Device Identifier) | Yes | Yes | 10614559100936 | 10614559100936 | 10614559100936 | 10614559100936 | 10614559100936 |

| LABELING SECTION | | | | | | | | |
|--|-----|-----|--|--|--|--|--|--|
| Device Description | No | Yes | Reusable Patient Return Electrode, Mega 2000, Adult, For Patients Weighing over 25lbs. (11.4Kg), 91cm Long x 51cm Wide | Reusable Patient Return Electrode, Mega 2000, Adult, For Patients Weighing over 25lbs. (11.4Kg), 91cm Long x 51cm Wide | Reusable Patient Return Electrode, Mega 2000, Adult, For Patients Weighing over 25lbs. (11.4Kg), 91cm Long x 51cm Wide | Reusable Patient Return Electrode, Mega 2000, Adult, For Patients Weighing over 25lbs. (11.4Kg), 91cm Long x 51cm Wide | Reusable Patient Return Electrode, Mega 2000, Adult, For Patients Weighing over 25lbs. (11.4Kg), 91cm Long x 51cm Wide | Reusable Patient Return Electrode, Mega 2000, Adult, For Patients Weighing over 25lbs. (11.4Kg), 91cm Long x 51cm Wide |
| <i>Device Labeled as "containing natural rubber latex or dry natural rubber"</i> | Yes | Yes | No | No | No | No | No | No |
| <i>Is the device labeled as "not made with natural rubber latex"?</i> | No | Yes | No | No | No | No | No | No |
| Does this product have a clinically relevant size? | No | No | No | No | No | No | No | No |
| Clinically Relevant Size (free text): | No | Yes | N/A | N/A | N/A | N/A | N/A | N/A |
| <i>What MRI Safety Information does the labeling contain?</i> | Yes | Yes | Labeling does not contain MRI safety information | Labeling does not contain MRI safety information | Labeling does not contain MRI safety information | Labeling does not contain MRI safety information | Labeling does not contain MRI safety information | Labeling does not contain MRI safety information |
| Brand Name | Yes | Yes | Mega 2000 | Mega 2000 | Mega 2000 | Mega 2000 | Mega 2000 | Mega 2000 |
| Product has special Storage and Handling Conditions? | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Storage and Handling Type 1? | No | Yes | Storage Environment Temperature | Storage Environment Temperature | Storage Environment Temperature | Storage Environment Temperature | Storage Environment Temperature | Storage Environment Temperature |
| Storage and Handling Low Value 1: | No | Yes | 5 | 5 | 5 | 5 | 5 | 5 |
| Storage and Handling High Value 1: | No | Yes | 50 | 50 | 50 | 50 | 50 | 50 |
| Storage and Handling Unit 1: | No | Yes | Degrees Celsius | Degrees Celsius | Degrees Celsius | Degrees Celsius | Degrees Celsius | Degrees Celsius |
| Storage and Handling Type 2? | No | Yes | Storage Environment Humidity | Storage Environment Humidity | Storage Environment Humidity | Storage Environment Humidity | Storage Environment Humidity | Storage Environment Humidity |
| Storage and Handling Low Value 2: | No | Yes | 15 | 15 | 15 | 15 | 15 | 15 |
| Storage and Handling High Value 2: | No | Yes | 95 | 95 | 95 | 95 | 95 | 95 |
| Storage and Handling Unit 2: | No | Yes | Percent (%) Relative Humidity | Percent (%) Relative Humidity | Percent (%) Relative Humidity | Percent (%) Relative Humidity | Percent (%) Relative Humidity | Percent (%) Relative Humidity |
| Customer Contact Phone: | No | Yes | +18015769669 | +18015769669 | +18015769669 | +18015769669 | +18015769669 | +18015769669 |
| Customer Contact Email: | No | Yes | megadyne.udi@megadyne.com | megadyne.udi@megadyne.com | megadyne.udi@megadyne.com | megadyne.udi@megadyne.com | megadyne.udi@megadyne.com | megadyne.udi@megadyne.com |
| PACKAGING SECTION | | | | | | | | |
| <i>Eaches per Box (device count)</i> | Yes | No | 1 | 1 | 1 | 1 | 1 | 1 |
| Eaches per Case | Yes | No | N/A | N/A | N/A | N/A | N/A | N/A |

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|--|-----|-----|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| Boxes per Case | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Instrument Net Weight | Yes | No | N/A | N/A | N/A | N/A | N/A |
| **Number of Case Layers per Tote | No | No | N/A, Non Jabil Sterilization Location | N/A, Non Jabil Sterilization Location | N/A, Non Jabil Sterilization Location | N/A, Non Jabil Sterilization Location | N/A, Non Jabil Sterilization Location |
| **Total Number of Cases per Tote | No | No | N/A, Non Jabil Sterilization Location | N/A, Non Jabil Sterilization Location | N/A, Non Jabil Sterilization Location | N/A, Non Jabil Sterilization Location | N/A, Non Jabil Sterilization Location |
| Is an unpackaged GTIN required? | No | No | No | No | No | No | No |
| Unpackaged GTIN | No | Yes | N/A | N/A | N/A | N/A | N/A |
| Is product Lot or Serial Controlled? | Yes | No | Serial Controlled | Serial Controlled | Serial Controlled | Serial Controlled | Serial Controlled |
| Product is managed by a Date of Manufacture (DOM)? | No | Yes | No | No | No | No | No |
| Product is managed by the Expiration Date? | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Product is managed by a Donation Identification Number? | No | Yes | No | No | No | No | No |
| Unit of Sale | Yes | No | EA | EA | EA | EA | EA |
| **Case Part Number | No | No | N/A | N/A | N/A | N/A | N/A |
| **Is Case Part Number New? | No | No | N/A | N/A | N/A | N/A | N/A |
| **Case / Pallet Configuration | No | No | N/A | N/A | N/A | N/A | N/A |
| **Dimensional Units of Measure (Inches / Pounds/ Grams per Cubic Centimeter) | | | | | | | |
| **Length (Each) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| **Length (Box) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| **Length (Case) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Width (Each) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Width (Box) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Width (Case) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Height (Each) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Height (Box) | Yes | No | N/A | N/A | N/A | N/A | N/A |

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|---|-----|-----|----------------|----------------|----------------|----------------|----------------|
| Height (Case) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Weight (Each) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Weight (Box) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Weight (Case) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| **Density (Box) | No | No | N/A | N/A | N/A | N/A | N/A |
| **Density (Case) | No | No | N/A | N/A | N/A | N/A | N/A |
| GTIN (Each) | Yes | Yes | 10614559100936 | 10614559100936 | 10614559100936 | 10614559100936 | 10614559100936 |
| GTIN (Box) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| GTIN (Case) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Single Unit Replacement Information (Inches) | | | | | | | |
| Single Unit Replacement for this product? | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Single Unit Replacement Product Code? | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Single Unit Pack-Out Configuration? | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Single Unit (Length) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Single Unit (Width) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Single Unit (Height) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Demonstration Unit Information (Inches) | | | | | | | |
| Is there a Demonstration Unit for this product? | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Demonstration Unit Product Code | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Demonstration Unit Pack-Out (Length) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Demonstration Unit Pack-Out (Width) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Demonstration Unit Pack-Out (Height) | Yes | No | N/A | N/A | N/A | N/A | N/A |
| STERILIZATION SECTION | | | | | | | |
| Packaged as Sterile? | Yes | Yes | No | No | No | No | No |

| | | | | | | | |
|--|-----|-----|-------------------|-------------------|-------------------|-------------------|-------------------|
| Sterilization Method | Yes | No | N/A | N/A | N/A | N/A | N/A |
| Customer required to sterilize product prior to use? | No | No | No | No | No | No | No |
| Sterilization Method Prior to Use (customer)? | No | Yes | N/A | N/A | N/A | N/A | N/A |
| CONTRACT ADMINISTRATION SECTION | | | | | | | |
| Product Type | Yes | No | 8 | 8 | 8 | 8 | 8 |
| Contract Type | Yes | No | 9 | 9 | 9 | 9 | 9 |
| Franchise Price Group | Yes | No | ES47 | ES47 | ES47 | ES47 | ES47 |
| DW Product Categorization | Yes | No | 308 - Ultracision | 308 - Ultracision | 308 - Ultracision | 308 - Ultracision | 308 - Ultracision |
| PRICING SECTION | | | | | | | |
| Federal Schedule Supply Indicator | Yes | No | No | No | No | No | No |
| Product will require back pricing? | Yes | No | Yes | Yes | Yes | Yes | Yes |
| COMMERCIAL FINANCE SECTION | | | | | | | |
| Minor Product Group Name and Number | Yes | No | 47110 | 47110 | 47110 | 47110 | 47110 |
| Product Tax Group | Yes | No | B2 | B2 | B2 | B2 | B2 |
| REGULATORY AFFAIRS SECTION | | | | | | | |
| <i>Product is a Kit?</i> | Yes | Yes | No | No | No | No | No |
| CE Mark? | Yes | No | Yes | Yes | Yes | Yes | **No |
| <i>Combination Product?</i> | No | Yes | No | No | No | No | No |
| Prescription Status (Rx or OTC)? | No | Yes | Rx | Rx | Rx | Rx | Rx |
| Labeler Duns Number | No | Yes | 185444825 | 185444825 | 185444825 | 185444825 | 185444825 |
| Device Exempt from Pre-Market Submission? | No | Yes | No | No | No | No | No |
| FDA Pre-Market Authorization Number: | No | Yes | K982826 | K982826 | K982826 | K982826 | K982826 |
| Supplement Number: | No | Yes | N/A | N/A | N/A | N/A | N/A |

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|--|-----|-----|--------------|--------------|--------------|--------------|--------------|
| Human Cell, Tissue or Cellular Tissue Based Product (HCT/P)? | No | Yes | No | No | No | No | No |
| FDA Device Class: | No | Yes | II | II | II | II | II |
| FDA Product Code: | No | Yes | GEI | GEI | GEI | GEI | GEI |
| GMDN Code: | No | Yes | **42551 | **42551 | **42551 | 42551 | 42551 |
| FDA Listing Number | No | Yes | D009827 | D009827 | D009827 | D009827 | D009827 |
| NEW PRODUCT & LIFECYCLE PLANNING SECTION | | | | | | | |
| Material Freight Group | Yes | No | 804R | 804R | 804R | 804R | 804R |
| Country of Origin | Yes | No | USA | USA | USA | USA | USA |
| HTS Code | Yes | No | 9018.90.6000 | 9018.90.6000 | 9018.90.6000 | 9018.90.6000 | 9018.90.6000 |