

PRODUCT MASTER DATA SPECIFICATION 0830							
Document Number: SPE003895		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
			0830	010830	020830	**030830	**040830
PRODUCT INFORMATION SECTION							
Packaging Assembly Number	No	No	N/A	N/A	N/A	** 0830 Rev E	** 0830 Rev E
Product Shelf Life (Months)	Yes	No	24	24	24	24	24
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 Hazardous	Not Hazardous	Not Hazardous	Not Hazardous	Not Hazardous
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	10614559101797	10614559101797	10614559101797	10614559101797	10614559101797

LABELING SECTION							
Device Description	No	Yes	Reusable Patient Return Electrode, Mega Soft, Single Cord, Adult, For Patients Weighing over 25lbs (11.4Kg), 117cm Long x 51cm Wide x 1.25cm Thick.	Reusable Patient Return Electrode, Mega Soft, Single Cord, Adult, For Patients Weighing over 25lbs (11.4Kg), 117cm Long x 51cm Wide x 1.25cm Thick.	Reusable Patient Return Electrode, Mega Soft, Single Cord, Adult, For Patients Weighing over 25lbs (11.4Kg), 117cm Long x 51cm Wide x 1.25cm Thick.	Reusable Patient Return Electrode, Mega Soft, Single Cord, Adult, For Patients Weighing over 25lbs (11.4Kg), 117cm Long x 51cm Wide x 1.25cm Thick.	Reusable Patient Return Electrode, Mega Soft, Single Cord, Adult, For Patients Weighing over 25lbs (11.4Kg), 117cm Long x 51cm Wide x 1.25cm Thick.
<i>Device Labeled as "containing natural rubber latex or dry natural rubber"</i>	Yes	Yes	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
Does this product have a clinically relevant size?	No	No	No	No	No	No	No
Clinically Relevant Size (free text):	No	Yes	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
<b>Brand Name</b>	Yes	Yes	Mega Soft	Mega Soft	Mega Soft	Mega Soft	Mega Soft
Product has special Storage and Handling Conditions?	No	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 and Handling Low Value 1:	No	Yes	5	5	5	5	5
Storage and Handling High Value 1:	No	Yes	50	50	50	50	50
Storage and Handling Unit 1:	No	Yes	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 and Handling Low Value 2:	No	Yes	15	15	15	15	15
Storage and Handling High Value 2:	No	Yes	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
Customer Contact Phone:	No	Yes	+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
PACKAGING SECTION							
<i>Eaches per Box (device count)</i>	Yes	No	1	1	1	1	1

Implement No Later Than:  
Implemented: 09/15/2020

Group: Specification  
Type: Product Master Data Specification

Eaches per Case	Yes	No	N/A	N/A	N/A	N/A	N/A
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	N/A	N/A	N/A	N/A
**Total Number of Cases per Tote	No	No	N/A	N/A	N/A	N/A	N/A
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

Implement No Later Than:  
Implemented: 09/15/2020

Group: Specification  
Type: Product Master Data Specification

Height (Box)	Yes	No	N/A	N/A	N/A	N/A	N/A
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	10614559101797	10614559101797	10614559101797	10614559101797	10614559101797
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							

Implement No Later Than:  
Implemented: 09/15/2020

Group: Specification  
Type: Product Master Data Specification

<b>Packaged as Sterile?</b>	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
<b>CONTRACT ADMINISTRATION SECTION</b>							
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
<b>PRICING SECTION</b>							
Federal Schedule Supply Indicator	Yes	No	No	No	No	No	No
Product will require back pricing?	Yes	No	Yes	Yes	Yes	Yes	Yes
<b>COMMERCIAL FINANCE SECTION</b>							
Minor Product Group Name and Number	Yes	No	47110	47110	47110	47110	47110
Product Tax Group	Yes	No	B2	B2	B2	B2	B2
<b>REGULATORY AFFAIRS SECTION</b>							
<b>Product is a Kit?</b>	Yes	Yes	No	No	No	No	No
CE Mark?	Yes	No	Yes	Yes	Yes	Yes	**No
<b>Combination Product?</b>	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	K021077	K021077	K021077	K021077	K021077

Implement No Later Than:  
Implemented: 09/15/2020

Group: Specification  
Type: Product Master Data Specification

Supplement Number:	No	Yes	N/A	N/A	N/A	N/A	N/A
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	D009829	D009829	D009829	D009829	D009829
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