

PRODUCT MASTER DATA SPECIFICATION

0063

Document Number:
SPE003833

ECN #:
ECN031351

Revision (letter):
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Master Data / GUDID Data Elements	MDM or SAP Value (Y/N)	LSP Upload Tool Value (Y/N)	Configuration	Configuration	Configuration	Configuration	Configuration
			0063				
PRODUCT INFORMATION SECTION							
Packaging Assembly Number	No	No	N/A				
Product Shelf Life (Months)	Yes	No	60				
Maximum Sterilization Dose	No	No	40 kGy				
Company Name	Yes	Yes	Megadyne Medical Products, Inc				
Single Use Product?	Yes	Yes	Yes				
Capital Indicator	Yes	No	No				
Associated Product Code Indicator	Yes	No	No				
Associated Product Code	No	No	N/A				
Special Storage Requirement Code / Conditions:	Yes	Yes	N/A				
Product SubType	Yes	No	Manufactured Finished Good				
Is this product software?	Yes	No	No				
Is product considered hazardous?	Yes	No	Not Hazardeous				
Device Part Marking Required?	Yes	Yes	No				
Device Part Marking Exemption Rationale (if "No" in Row 26)	Yes	Yes	Single Use Device				

GTIN (Primary Device Identifier)	Yes	Yes	10614559100561				
LABELING SECTION							
Device Description	No	Yes	E-Z Clean Electrosurgical L-Wire Hook Laparoscopic Electrode for use with All-In-One Suction Irrigation Pencil, 5mm x 32cm, Single-Use				
<i>Device Labeled as "containing natural rubber latex or dry natural rubber"</i>	Yes	Yes	No				
<i>Is the device labeled as "not made with natural rubber latex"?</i>	No	Yes	No				
Does this product have a clinically relevant size?	No	No	No				
Clinically Relevant Size (free text):	No	Yes	N/A				
<i>What MRI Safety Information does the labeling contain?</i>	Yes	Yes	Labeling does not contain MRI safety information				
Brand Name	Yes	Yes	Megadyne				
Product has special Storage and Handling Conditions?	No	Yes	Yes				
Storage and Handling Type 1?	No	Yes	Storage Environment Temperature				
Storage and Handling Low Value 1:	No	Yes	5				
Storage and Handling High Value 1:	No	Yes	50				
Storage and Handling Unit 1:	No	Yes	Degrees Celsius				
Storage and Handling Type 2?	No	Yes	Storage Environment Humidity				
Storage and Handling Low Value 2:	No	Yes	15				
Storage and Handling High Value 2:	No	Yes	95				
Storage and Handling Unit 2:	No	Yes	Percent (%) Relative Humidity				
Customer Contact Phone:	No	Yes	+18015769669				
Customer Contact Email:	No	Yes	megadyne.udi@megadyne.com				
PACKAGING SECTION							

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Group: Specification
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Eaches per Box (device count)	Yes	No	5				
Eaches per Case	Yes	No	40				
Boxes per Case	Yes	No	8				
Instrument Net Weight	Yes	No	0.8				
Is an unpackaged GTIN required?	No	No	No				
Unpackaged GTIN	No	Yes	N/A				
Is product Lot or Serial Controlled?	Yes	No	Lot Controlled				
Product is managed by a Date of Manufacture (DOM)?	No	Yes	No				
Product is managed by the Expiration Date?	Yes	Yes	Yes				
Product is managed by a Donation Identification Number?	No	Yes	No				
Unit of Sale	Yes	No	Box				
Dimensional Units of Measure (Inches / Weight)							
Depth (Each)	Yes	No	N/A				
Depth (Box)	Yes	No	4				
Depth (Case)	Yes	No	12				
Width (Each)	Yes	No	N/A				
Width (Box)	Yes	No	20				
Width (Case)	Yes	No	20				
Height (Each)	Yes	No	N/A				
Height (Box)	Yes	No	4				
Height (Case)	Yes	No	20				
Weight (Each)	Yes	No	N/A				
Weight (Box)	Yes	No	0.8				

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Weight (Case)	Yes	No	8.2				
GTIN (Each)	Yes	Yes	10614559100561				
GTIN (Box)	Yes	No	30614559100565				
GTIN (Case)	Yes	No	50614559100569				
Single Unit Replacement Information (Inches)							
Single Unit Replacement for this product?	Yes	No	N/A				
Single Unit Replacement Product Code?	Yes	No	N/A				
Single Unit Pack-Out Configuration?	Yes	No	N/A				
Single Unit (Length)	Yes	No	N/A				
Single Unit (Width)	Yes	No	N/A				
Single Unit (Height)	Yes	No	N/A				
Demonstration Unit Information (Inches)							
Is there a Demonstratiion Unit for this product?	Yes	No	N/A				
Demonstration Unit Product Code	Yes	No	N/A				
Demonstration Unit Pack-Out (Depth)	Yes	No	N/A				
Demonstration Unit Pack-Out (Width)	Yes	No	N/A				
Demonstration Unit Pack-Out (Height)	Yes	No	N/A				
STERILIZATION SECTION							
Packaged as Sterile?	Yes	Yes	Yes				
Sterilization Method	Yes	No	GAMMA				
Customer required to sterilize product prior to use?	No	No	No				
Sterilization Method Prior to Use (customer)?	No	Yes	N/A				
CONTRACT ADMINISTRATION SECTION							
Product Type	Yes	No	8				

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Contract Type	Yes	No	9				
Franchise Price Group	Yes	No	ES50				
DW Product Categorization	Yes	No	308 - Ultracision				
PRICING SECTION							
Federal Schedule Supply Indicator	Yes	No	No				
Product will require back pricing?	Yes	No	Yes				
COMMERCIAL FINANCE SECTION							
Minor Product Group Name and Number	Yes	No	47110				
Product Tax Group	Yes	No	C1				
REGULATORY AFFAIRS SECTION							
Product is a Kit?	Yes	Yes	No				
CE Mark?	Yes	No	Yes				
Combination Product?	No	Yes	No				
Prescription Status (Rx or OTC)?	No	Yes	Rx				
Labeler Duns Number	No	Yes	185444825				
Device Exempt from Pre-Market Submission?	No	Yes	No				
FDA Pre-Market Authorization Number:	No	Yes	K922002				
Supplement Number:	No	Yes	N/A				
Human Cell, Tissue or Cellular Tissue Based Product (HCT/P)?	No	Yes	No				
FDA Device Class:	No	Yes	II				
FDA Product Code:	No	Yes	GEI				
GMDN Code:	No	Yes	**61875				
FDA Listing Number	No	Yes	D009826				

NEW PRODUCT & LIFECYCLE PLANNING SECTION							
Material Freight Group	Yes	No	804R				
Country of Origin	Yes	No	USA				
HTS Code	Yes	No	9018.90.6000				