PRODUCT MASTER DATA SPECIFICATION
0022

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SPE003778

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ECN031251

Revision (letter):
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Master Data / GUDID Data Elements	MDM or SAP Value (Y/N)	LSP Upload Tool Value (Y/N)	Configuration 0022	Configuration 010022	Configuration
PRODUCT INFORMATION SECTION					
Packaging Assembly Number	No	No	N/A	N/A	
Product Shelf Life (Months)	Yes	No	60	60	
Maximum Sterilization Dose	No	No	55 kGy	55 kGy	
Company Name	Yes	Yes	Megadyne Medical Products, Inc	Megadyne Medical Products, Inc	
Single Use Product?	Yes	Yes	Yes	Yes	
Capital Indicator	Yes	No	No	No	
Associated Product Code Indicator	Yes	No	No	No	
Associated Product Code	No	No	N/A	N/A	
Special Storage Requirement Code / Conditions:	Yes	Yes	N/A	N/A	
Product SubType	Yes	No	Manufactured Finished Good	Manufactured Finished Good	
Is this product software?	Yes	No	No	No	
Is product considered hazardous?	Yes	No	Not Hazardeous	Not Hazardeous	
Device Part Marking Required?	Yes	Yes	No	No	
Device Part Marking Exemption Rationale (if "No" in Row 26)	Yes	Yes	Single Use Device	Single Use Device	

GTIN (Primary Device Identifier)	Yes	Yes	10614559100394	10614559100394	
LABELING SECTION					
Device Description	No	Yes	Electrosurgical Laparoscopic Electrode, Needle, 33 cm., Single-	Electrosurgical Laparoscopic Electrode, Needle, 33 cm., Single-	
Device Labeled as "containing natural rubber latex or dry natural rubber"	Yes	Yes	No	No	
Is the device labeled as "not made with natural rubber latex"?	No	Yes	No	No	
Does this product have a clinically relevant size?	No	No	No	No	
Clinically Relevant Size (free text):	No	Yes	N/A	N/A	
What MRI Safety Information does the labeling contain?	Yes	Yes	Labeling does not contain MRI safety information	Labeling does not contain MRI safety information	
Brand Name	Yes	Yes	Megadyne	Megadyne	
Product has special Storage and Handling Conditions?	No	Yes	Yes	Yes	
Storage and Handling Type 1?	No	Yes	Storage Environment Temperature	Storage Environment Temperature	
Storage and Handling Low Value 1:	No	Yes	5	5	
Storage and Handling High Value 1:	No	Yes	50	50	
Storage and Handling Unit 1:	No	Yes	Degrees Celsius	Degrees Celsius	
Storage and Handling Type 2?	No	Yes	Storage Environment Humidity	Storage Environment Humidity	
Storage and Handling Low Value 2:	No	Yes	15	15	
Storage and Handling High Value 2:	No	Yes	95	95	
Storage and Handling Unit 2:	No	Yes	Percent (%) Relative Humidity	Percent (%) Relative Humidity	
Customer Contact Phone:	No	Yes	+18015769669	+18015769669	
Customer Contact Email:	No	Yes	megadyne.udi@megadyne.com	megadyne.udi@megadyne.com	
PACKAGING SECTION					
Eaches per Box (device count)	Yes	No	6	6	
Eaches per Case	Yes	No	240	240	

Boxes per Case	Yes	No	40	40	
Instrument Net Weight	Yes	No	0.7	0.7	
**Number of Case Layers per Tote	No	No	N/A	N/A	
**Total Number of Cases per Tote	No	No	N/A	N/A	
Is an unpackaged GTIN required?	No	No	No	No	
Unpackaged GTIN	No	Yes	N/A	N/A	
Is product Lot or Serial Controlled?	Yes	No	Lot Controlled	Lot Controlled	
Product is managed by a Date of Manufacture (DOM)?	No	Yes	No	No	
Product is managed by the Expiration Date?	Yes	Yes	Yes	Yes	
Product is managed by a Donation Identification Number?	No	Yes	No	No	
Unit of Sale	Yes	No	Box	Box	
**Case Part Number	No	No	N/A	N/A	
**Is Case Part Number New?	No	No	N/A	N/A	
**Case / Pallet Configuration	No	No	N/A	N/A	
Dimensional Units of Measure (Inches / Pounds/ Grams per Cubic Centimeter)	////	////	////	////	////
**Length (Each)	Yes	No	N/A	N/A	
**Length (Box)	Yes	No	N/A	N/A	
**Length (Case)	Yes	No	N/A	N/A	
Width (Each)	Yes	No	N/A	N/A	
Width (Box)	Yes	No	16	16	
Width (Case)	Yes	No	10.5	10.5	
Height (Each)	Yes	No	N/A	N/A	
Height (Box)	Yes	No	2	2	

	Yes/No	Yes/No	Value 1	Value 2	
Height (Case)	Yes	No	16.25	16.25	
Weight (Each)	Yes	No	N/A	N/A	
Weight (Box)	Yes	No	0.7	0.7	
Weight (Case)	Yes	No	28.55	28.55	
**Density (Box)	No	No	N/A	N/A	
**Density (Case)	No	No	N/A	N/A	
GTIN (Each)	Yes	Yes	10614559100394	10614559100394	
GTIN (Box)	Yes	No	30614559100398	30614559100398	
GTIN (Case)	Yes	No	50614559100392	50614559100392	
Single Unit Replacement Information (Inches)	///	///	///	///	///
Single Unit Replacement for this product?	Yes	No	N/A	N/A	
Single Unit Replacement Product Code?	Yes	No	N/A	N/A	
Single Unit Pack-Out Configuration?	Yes	No	N/A	N/A	
Single Unit (Length)	Yes	No	N/A	N/A	
Single Unit (Width)	Yes	No	N/A	N/A	
Single Unit (Height)	Yes	No	N/A	N/A	
Demonstration Unit Information (Inches)	///	///	///	///	///
Is there a Demonstration Unit for this product?	Yes	No	N/A	N/A	
Demonstration Unit Product Code	Yes	No	N/A	N/A	
Demonstration Unit Pack-Out (Length)	Yes	No	N/A	N/A	
Demonstration Unit Pack-Out (Width)	Yes	No	N/A	N/A	
Demonstration Unit Pack-Out (Height)	Yes	No	N/A	N/A	
STERILIZATION SECTION	///	///	///	///	///
Packaged as Sterile?	Yes	Yes	Yes	Yes	

Sterilization Method	Yes	No	GAMMA	GAMMA	
Customer required to sterilize product prior to use?	No	No	No	No	
Sterilization Method Prior to Use (customer)?	No	Yes	N/A	N/A	
CONTRACT ADMINISTRATION SECTION					
Product Type	Yes	No	8	8	
Contract Type	Yes	No	9	9	
Franchise Price Group	Yes	No	ES49	ES49	
DW Product Categorization	Yes	No	308 - Ultracision	308 - Ultracision	
PRICING SECTION					
Federal Schedule Supply Indicator	Yes	No	No	No	
Product will require back pricing?	Yes	No	Yes	Yes	
COMMERCIAL FINANCE SECTION					
Minor Product Group Name and Number	Yes	No	47110	47110	
Product Tax Group	Yes	No	C1	C1	
REGULATORY AFFAIRS SECTION					
Product is a Kit?	Yes	Yes	No	No	
CE Mark?	Yes	No	Yes	Yes	
Combination Product?	No	Yes	No	No	
Prescription Status (Rx or OTC)?	No	Yes	Rx	Rx	
Labeler Duns Number	No	Yes	185444825	185444825	
Device Exempt from Pre-Market Submission?	No	Yes	No	No	
FDA Pre-Market Authorization Number:	No	Yes	K913281	K913281	
Supplement Number:	No	Yes	N/A	N/A	

Human Cell, Tissue or Cellular Tissue Based Product (HCT/P)?	No	Yes	No	No	
FDA Device Class:	No	Yes	II	II	
FDA Product Code:	No	Yes	GEI	GEI	
GMDN Code:	No	Yes	**61875	**61875	
FDA Listing Number	No	Yes	D009819	D009819	
NEW PRODUCT & LIFECYCLE PLANNING SECTION	/////	/////	/////////	/////////	/////////
Material Freight Group	Yes	No	804R	804R	
Country of Origin	Yes	No	USA	USA	
HTS Code	Yes	No	9018.90.6000	9018.90.6000	