



Document Number: SCN075729

Revision: B

Group: Scanned (Hardcopy) Item

Type: ECR/ECP supportive documents

State: In Review

Latest Released: NO

Implemented Date:

Stamp Date: Thursday, September 3, 2020 10:07:22 AM EST

STRATEGY PLAN FORM

Introduction

Project Name	Update Megadyne Labeling per International Labeling Requirements (RA-DOC-022)
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Originated by: Felix Gutierrez / External Manufacturing Engineer	SEE EPI ESIG
	Date

Review / Approval	
	<div><div><u>Angel Maldonado</u></div><div>Contract Account Manager (Supplier Relationship Manager)</div><div><u>SEE EPI ESIG</u></div><div>Date</div></div>
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	<div><div><u>Kent Allen</u></div><div>EM Quality Manager</div><div><u>SEE EPI ESIG</u></div><div>Date</div></div>

Revision	Summary
A	Original
B	Revised to close Cp0235. Deliverables added to the supporting files section.

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Scope

Project Scope	Megadyne product labeling is being updated to meet the international labeling requirements in order to distribute Megadyne product globally. These labeling changes will require a product mod code change from 00 to 01.
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Product Name and Codes	Refer to Attachment 1 – Megadyne Product Codes
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Product Category	The identified product code(s) are a Category <u>E</u> per CP0235 .
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Responsible Areas	The following functional areas have been identified as those responsible for deliverables:
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Functional Area	Strategy/Deliverable (Content or Reference)	Person Responsible
Life Cycle	2019-MKT-DCO-057	Brian Bertke
	- E-Z Clean, Blade (3900350) ** See Attachment: 3900350-01 Pouch 8.27 X .98 (0014) (MV)	
	- E-Z Clean, Blade (3900351) ** See Attachment: 3900351-01 Pouch 8.27 X .98 (0014A) (MV)	
	- E-Z Clean, Blade (3900352) ** See Attachment: 3900352-01 Pouch 8.27 X .98 (0014AM) (MV)	
	- E-Z Clean, Blade (3900353) ** See Attachment: 3900353-01 Pouch 8.27 X .98 (0014AMP) (MV)	
	- E-Z Clean, Blade (3900354) ** See Attachment: 3900354-01 Pouch 8.27 X .98 (0014AP) (MV)	
	- E-Z Clean, Blade (3900355) ** See Attachment: 3900355-01 Pouch 8.27 X .98 (0014M) (MV)-1	
	- E-Z Clean, Blade (3900356) ** See Attachment: 3900356-01 Pouch 8.27 X .98 (0014MP) (MV)-1	
	- E-Z Clean, Blade (3900357) ** See Attachment: 3900357-01 Pouch 8.27 X .98 (C117) (MV)	
	- E-Z Clean, Blade (3900378) ** See Attachment: 3900378-01 Pouch 8.27 X .98 (C117J) (MV)-1	
	- E-Z Clean, Blade (3900358) ** See Attachment: 3900358-01 Pouch 8.27 X .98 (C117M) (MV)-1	
	- E-Z Clean, Blade (3900359) ** See Attachment: 3900359-01 Pouch 8.27 X .98 (0009) (MV)-1	
	- LABEL, CASE BOX, E-Z CLEAN, 0014 (3151516)	

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	** See Attachment: 3151516-01 Label Case Box E-Z	
	- E-Z Clean, Blade (3151507)	
	** See Attachment: 3151507-01 Label Case Box E-Z	
	- E-Z Clean, Blade (3151508)	
	** See Attachment: 3151508-01 Label Case Box E-Z	
	- E-Z Clean, Blade (3151509)	
	** See Attachment: 3151509-01 Label Case Box E-Z	
	- E-Z Clean, Blade (3151510)	
	** See Attachment: 3151510-01 Label Case Box E-Z	
	- E-Z Clean, Blade (3151511)	
	** See Attachment: 3151511-01 Label Case Box Fla	
	- E-Z Clean, Blade (3151512)	
	** See Attachment: 3151512-01 Label Case Box E-Z	
	- C117 CASE BOX (3151545)	
	** See Attachment: 3151545-01 Label E-Z Clean Fl	
	- E-Z Clean, Blade (3151513)	
	** See Attachment: 3151513-01 Label E-Z Clean Fl	
	- C117M CASE BOX (3151546)	
	** See Attachment: 3151546-01 Label E-Z Clean Fl	
	- E-Z Clean, Blade (3151514)	
	** See Attachment: 3151514-01 Label Case Box E-Z	
	- E-Z Clean, Blade (3151496)	
	** See Attachment: 3151496-01 Label E-Z Clean Fl	
	- E-Z Clean, Blade (3151497)	
	** See Attachment: 3151497-01 Label E-Z Clean Fl	
	- E-Z Clean, Blade (3151498)	
	** See Attachment: 3151498-01 Label E-Z Clean Fl	
	- E-Z Clean, Blade (3151499)	
	** See Attachment: 3151499-01 Label E-Z Clean Pr	
	- E-Z Clean, Blade (3151500)	
	** See Attachment: 3151500-01 Label E-Z Clean Pr	
	- E-Z Clean, Blade (3151501)	
	** See Attachment: 3151501-01 Label E-Z Clean Fl	
	- E-Z Clean, Blade (3151502)	
	** See Attachment: 3151502-01 Label Unit Box E-Z	
	- E-Z Clean, Blade (3151503)	
	** See Attachment: 3151503-01 Label E-Z Clean Fl	
	- E-Z Clean, Blade (3151504)	
	** See Attachment: 3151504-01 Label E-Z Clean Fl	
	- E-Z Clean, Blade (3151505)	
	** See Attachment: 3151505-01 Label E-Z Clean Fl	
	- E-Z Clean, Blade (3151506)	
	** See Attachment: 3151506-01 Label Unit Box E-Z	
Life Cycle	2019-MKT-DCO-052	Brian Bertke
	- IFU, E-Z Clean, Electrode (3000338)	
	** See Attachment: 3000338, IFU, E-Z Clean, Electrode	
Life Cycle	2019-MKT-DCO-058	Brian Bertke
	- UNIT BOX, PRE-PRINTED 8-3/4 X 5-7/8 X 1 (3200203)	
	** See Attachment: 3200203-01 Unit Box Pre-Printed 8.75 X 5.88 X 1.0-1	
Life Cycle	2019-ENG-DCO-086	Brian Bertke
	- Electrode, Flat Blade, Insulated/Coated, 6.5, Pouched (MV) - Assembly (0014)	
	** See Attachment: 0014 Pouched Electrode Flat Blade Insulated Coated 6.5 (MV)-1	
	- Electrode, Flat Blade, Insulated/Coated, 4.0, Pouched (MV) -	

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	Assembly (0014A) ** See Attachment: 0014A Pouched Electrode_ Flat Blade_ Insulated_ Coated 4.0 (MV) Assy -1	
	- Electrode, Flat Blade, Modified, Insulated/Coated, 4.0, Pouched (MV) - Assembly (0014AM) ** See Attachment: 0014AM Pouched Electrode_ Flat Blade_ Modified_ Insulated_ Coated 4.0 (MV) Assy	
	- Electrode, E-Z Clean Precision, Modified, Pouched, 4.00 (0014AMP) ** See Attachment: 0014AMP Electrode_ E-Z Clean Precision_ Modified_ Pouched 4.0	
	- Electrode, E-Z Clean Precision, Pouched, 4.00 (0014AP) ** See Attachment: 0014AP Electrode_ E-Z Clean Precision_ Pouched 4.0-1	
	- Electrode, Flat Blade, Modified, Insulated/Coated, 6.5, Pouched (MV) - Assembly (0014M) ** See Attachment: 0014M Pouched Electrode_ Flat Blade Mod_ Insulated Coated 6.5	
	- Electrode, 4.72 Blade, Custom, Insulated/Coated, Pouched (MV) - Assembly (C117) ** See Attachment: C117 Pouched Electrode_ 4	
	- C117J-Electrode, 4.72 Blade, Custom, Insulated/Coated, Pouched (MV) - Assembly (C117J) ** See Attachment: C117J Pouched Electrode 4.72 Blade Insulated Coated	
	- Electrode, 4.72 Blade, Modified, Custom, Insulated/Coated, Pouched (MV) - Assembly (C117M) ** See Attachment: C117M Pouched Electrode_ 4	
	- Electrode, Ball, 5.00 (MV) (0009) ** See Attachment: 0009 Pouched Electrode_ E-Z Clean_ Ball_ 5.0 Ball Assembly	
Life Cycle	2019-MKT-DCO-074	Brian Bertke
	- Label, Electrode, Bulk Non-Sterile (0013BN) (3151555) ** See Attachment: 3151555-01 Label_ Electrode_ Bu-1	
	- Label, Electrode, Bulk Non-Sterile (0013MBN) (3151556) ** See Attachment: 3151556-01 Label_ Needle_ Bulk	
Life Cycle	2019-ENG-DCO-115	Brian Bertke
	- EZ Clean, Needles, Bulk Non-Sterile, 2.75 (Qty. 100)- Top Assy (0013BN) ** See Attachment: 0013BN Electrode_ Bulk Non-Sterile 2.75	
	- Electrode, Needle, Modified, Insulated/Coated, 2.75, Bulk Non-Sterile (MV) (0013MBN) ** See Attachment: 0013MBN Needle_ Bulk Non-Sterile 2.75	

ATTACHMENT 1

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Megadyne Product Codes

<u>Product Codes</u>	<u>Description</u>
0014	Electrode, Flat Blade, Insulated/Coated, 6.5, Pouched (MV) - Assembly
0014A	Electrode, Flat Blade, Insulated/Coated, 4.0, Pouched (MV) - Assembly
0014AM	Electrode, Flat Blade, Modified, Insulated/Coated, 4.0, Pouched (MV) - Assembly
0014AMP	Electrode, E-Z Clean Precision, Modified, Pouched, 4.00
0014AP	Electrode, E-Z Clean Precision, Pouched, 4.00
0014M	Electrode, Flat Blade, Modified, Insulated/Coated, 6.5, Pouched (MV) - Assembly
C117J	C117J-Electrode, 4.72 Blade, Custom, Insulated/Coated, Pouched (MV) - Assembly
C117M	Electrode, 4.72 Blade, Modified, Custom, Insulated/Coated, Pouched (MV) - Assembly
0009	Electrode, Ball, 5.00 (MV)
0013BN	EZ Clean, Needles, Bulk Non-Sterile, 2.75 (Qty. 100)- Top Assy
0013MBN	Electrode, Needle, Modified, Insulated/Coated, 2.75, Bulk Non-Sterile (MV)