**STRATEGY PLAN FORM**

Introduction

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| Project Name | Update Megadyne Labeling per International Labeling Requirements (RA-DOC-023) |

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| **Originated by: Felix Gutierrez / External Manufacturing Engineer SEE EPI ESIG** | | |
|  |  | Date |

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| Review / Approval | Angel Maldonado SEE EPI ESIG  Contract Account Manager (Supplier Relationship Manager) Date  Kofi Baah SEE EPI ESIG  Engineering Manager (Technical Operations Manager) Date  Kent Allen SEE EPI ESIG  EM Quality Manager Date |

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| Revision | Summary |
| A | Original |

Scope

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| 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 \_E\_\_ 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-170 | Brian Bertke |
|  | * LABEL, MONOPOLAR ELECTROSURGICAL CABLE (3151975) |  |
| Life Cycle | 2019-MKT-DCO-171 | Brian Bertke |
|  | * IFU, Non-Sterile Reusable Monopolar Electrosurgical Cable (Ten foot) (3000370) |  |
| Life Cycle | 2019-ENG-DCO-347 | Brian Bertke |
|  | * Bagged, Monopolar, Electrosurgical Connecting Cable -Assy (0075) |  |
| Life Cycle | 2019-MKT-DCO-172 | Brian Bertke |
|  | * Reusable monopolar cable-Descriptor translation (3151967) |  |
| Life Cycle | 2019-MKT-DCO-143 | Brian Bertke |
|  | * Artwork Label Pouch, 1.19 X 15.75 (0021) (3900428) |  |
|  | * Artwork Label Pouch, 1.19 X 15.75 (0022) (3900429) |  |
|  | * Artwork Label Pouch, 0026S (3900430) |  |
|  | * Artwork Label Pouch, 0100 (3900431) |  |
|  | * Artwork Label Pouch, Lap Electrode, L-Wire 45 cm (0100L) (3151796) |  |
|  | * Artwork Label Pouch, Lap Electrode, L-Wire, Split Stem 45 cm (0100LS) (3151797) |  |
|  | * Artwork Label Pouch, 0100S (3900432) |  |
|  | * Artwork Label Pouch, 0105S (3900433) |  |
|  | * Artwork Label Pouch, 1.19 X 15.75 (0022S) (3900434) |  |
|  | * Label, Unit Box, Lap Electrode, J-Hook, (0021) (3151798) |  |
|  | * Label, Unit Box, Lap Electrode, Needle (0022) (3151799) |  |
|  | * Label, Unit Box, Lap Electrode, O-Wire Split Stem, (0026S) (3151800) |  |
|  | * Label, Unit Box, Lap Electrode, L-Wire, (0100) (3151801) |  |
|  | * Label, Unit Box, Lap Electrode, L-Wire 45cm (0100L) (3151802) |  |
|  | * Label, Unit Box, Lap Electrode, L-Wire, Split Stem, 45cm (0100LS) (3151803) |  |
|  | * Label, Unit Box, Lap Electrode, L-Wire Split Stem, (0100S) (3151804) |  |
|  | * Label, Unit Box, Lap Electrode, J-Wire Split Stem, (0105S) (3151805) |  |
|  | * Label, Unit Box, Lap Electrode, Needle, Split Stem, (0022S) (3151806) |  |
|  | * Label, Case Box Lap Electrode, J-Hook (0021) (3151807) |  |
|  | * Label, Case Box, Lap Electrode, Needle (0022) (3151808) |  |
|  | * Label, Case Box, Lap Electrode, O-Wire Split Stem, (0026S) (3151809) |  |
|  | * Label, Case Box, Lap Electrode, L-Wire, (0100) (3151810) |  |
|  | * Label, Case Box, Lap Electrode, L-Wire, (0100L) (3151811) |  |
|  | * Label, Case Box, Lap Electrode, L-Wire, Split Stem 45cm (0100LS) (3151812) |  |
|  | * Label, Case Box, Lap Electrode, L-Wire Split Stem, (0100S) (3151813) |  |
|  | * Label, Case Box, Lap Electrode, J-Wire Split Stem, (0105S) (3151814) |  |
|  | * Label, Case Box, Lap Electrode, Needle, Split Stem, (0022S) (3151815) |  |
| Life Cycle | 2019-MKT-DCO-052 | Brian Bertke |
|  | * IFU, E-Z Clean, Electrode (3000338) |  |
| Life Cycle | 2019-MKT-DCO-121 | Brian Bertke |
|  | * UNIT BOX, PRE-PRINTED 2.0 X 1.2 X 15.7 (MV) "GENERIC" (3200210) |  |
| Life Cycle | 2019-ENG-DCO-236 | Brian Bertke |
|  | * Pouched/Boxed/Labeled Laparoscopic Electrode, J-Hook - Assembly (MV) (0021) |  |
|  | * Pouched/Boxed/Labeled Laparoscopic Electrode, Needle - Assembly (MV) (0022) |  |
|  | * Pouched/Boxed/Labeled Laparoscopic Electrode, O-Wire, Split Stem - Assembly (MV) (0026S) |  |
|  | * Pouched/Boxed/Labeled Laparoscopic Electrode, L-Wire - Assembly (MV) (0100) |  |
|  | * Lap Electrode, L-Wire 45cm EZ Clean (0100L) |  |
|  | * Lap Electrode, L-Wire 45cm Split Stem EZ Clean (0100LS) |  |
|  | * Pouched/Boxed/Labeled Laparoscopic Electrode, L-Wire, Split Stem - Assembly (MV) (0100S) |  |
|  | * Pouched/Boxed/Labeled Laparoscopic Electrode, J-Wire, Split Stem - Assembly (MV) (0105S) |  |
|  | * Pouched/Boxed/Labeled Laparoscopic Electrode, Needle, Split Stem - Assembly (MV) (0022S) |  |

ATTACHMENT 1

Megadyne Product Codes

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| **Product Codes** | **Description** |
| 0075 | Bagged, Monopolar, Electrosurgical Connecting Cable -Assy |
| 0021 | Pouched/Boxed/Labeled Laparoscopic Electrode, J-Hook - Assembly (MV) |
| 0022 | Pouched/Boxed/Labeled Laparoscopic Electrode, Needle - Assembly (MV) |
| 0026S | Pouched/Boxed/Labeled Laparoscopic Electrode, O-Wire, Split Stem - Assembly (MV) |
| 0100 | Pouched/Boxed/Labeled Laparoscopic Electrode, L-Wire - Assembly (MV) |
| 0100L | Lap Electrode, L-Wire 45cm EZ Clean |
| 0100LS | Lap Electrode, L-Wire 45cm Split Stem EZ Clean |
| 0100S | Pouched/Boxed/Labeled Laparoscopic Electrode, L-Wire, Split Stem - Assembly (MV) |
| 0105S | Pouched/Boxed/Labeled Laparoscopic Electrode, J-Wire, Split Stem - Assembly (MV) |
| 0022S | Pouched/Boxed/Labeled Laparoscopic Electrode, Needle, Split Stem - Assembly (MV) |