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Quality Assurance Plan

Project/Product Name: Megadyne Medical Products Inc. Capital Equipment
Product Codes: 1000; 0800; 0800S; 0830; 0830S; 0835; 0835S; 0840; 0840S; 0845; 0845S; 0846; 0846S; 0847; 0847S; 0848; 0847S

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QUALITY PLAN

1 Purpose

This Quality Assurance Plan delineates the key objectives and briefly describes the methods that will be used in the service and repair process for Megadyne Medical Products Inc. Capital Equipment. This document will also provide project specific guidelines when no company standard or document is available for reference. Megadyne Medical Products Inc. Capital Equipment (Megadyne) is an externally designed and manufactured product not covered by an Ethicon Endo Surgery, Inc. (Ethicon) CP0258 project; therefore, no Design Plan document exists within EES systems.

This Quality Assurance Plan is considered a supplement to the quality agreement between Megadyne and EES and is intended to communicate service and repair strategies specific to Megadyne Capital Equipment that will be utilized in the execution of the project. The current Quality Agreement can be located within ADAPTIV under the Ethicon document number 100571196.

2 Scope

This plan will cover all servicing activities for the following Megadyne Medical Products Inc, 11506 South State Street, Draper, UT 84020.

1000, Megadyne™ Mega Power™ 1000 Electrosurgical Generator
800; 800S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – Mega 2000
0830; 0830S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft
0835; 0835S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft Dual
0840; 0840S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft Pediatric
0845; 0845S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft Universal
0846; 0846S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft Universal Dual
0847; 0847S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft Universal Plus
0848; 0848S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft Universal Dual Sample

3 Quality System

The governing Quality System for design and development of the product will comply with Megadyne deliverables as outlined in the Megadyne new product development process. EES maintains a recognized quality system that adheres to CFR 21 Part 820 and EN ISO 13485: 2016 or later. The systems and processes used by the service center fall within that quality system and/or those outlined in the Megadyne quality system. The two systems will be used during the analysis, service, and repair of the devices described above. The Quality Plan (this document) will define or point to the specific forms and procedures to be utilized in instances where prescribed EES Cincinnati deliverables may be met. Individual sections within this Quality Assurance Plan also address project elements that will be driven by the Ethicon Endo Surgery Cincinnati Quality System.

3.1 Risk Management

Megadyne is responsible for assuring that risks associated with products are identified and assessed throughout the product lifecycle and ensures that measures are taken to minimize, communicate, and control risk. Megadyne is responsible for assuring any residual risk is understood by management and communicated effectively to customers, healthcare professionals and regulatory agencies wherever appropriate. EES is responsible for communicating back to Megadyne any discovered risks associated

(including relevant risk mitigation) to storage, handling, repairing, delivery, labeling, relabeling, or re-packaging of product under their control.

4 Reference Documents

Johnson and Johnson Enterprise Standards
Worldwide Records and Information Management; Enterprise Retention Schedule Standard: WWRIM Standard RIMS-12

Ethicon Endo Surgery Inc. Documents
CP0001, Document and Data Control Procedure
CP0030, Statistical Techniques Procedure
CP0160, Change Control/Approval Matrix
CP0190, Requirements for Control of Inspection, Measuring and Test Equipment
CP000407, Servicing Procedure
PR-0000256, Franchise Procedure for Control of Nonconforming Product and Nonconforming Processing
PR-0000368, Franchise Procedure for Tracking and Trending of Quality Systems Data
PR-0000394, Intra-Company Quality Agreement Process (Shared)
PR575-001, Franchise CAPA Procedure (Shared)
PR001566, Megadyne™ Mega Power™ 1000 Electrosurgical Generator Service and Repair Instructions
PR001567, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes Service and Repair Instructions
PRC086802, Megadyne™ Mega Power™ 1000 Electrosurgical Generator Service Transfer
PRC090330, Megadyne Mega Soft Service Validation Summary Report
WE0137, Process Specification Procedure
WE001142, Receiving for Service Center
WE001143, Decontamination Procedure
WE001145, Electrostatic Protection Procedure
WE001147, Handling, Storage, Packaging, And Shipping Product for The Service Center
WE001150, Spare Part and Material Control for EES Part Depot
WE001302, Product Batch Certification and Release Work Instruction for Cincinnati Service and Repair
WE001369, Incoming Component Part Inspection Procedure for The EES Part Depot
WE001534, Establishment and Certification of Service Depot, Field Service, and Parts Depot Centers
100254122, Franchise Work Instruction for EtQ Nonconformance Process (Shared)
100095458, Franchise Records Retention Schedule
100538251, Franchise Complaint Policy (Shared)
100571196, Quality Agreement EES LLC EES INC Megadyne
100583095, Franchise Approved Supplier List Management (Shared)
100584788 Franchise Policy for Validation (Shared)

Megadyne Documents
3000144-01 Megadyne Mega Power Field Calibration Manual
3000145-01 Megadyne Mega Power Trouble Shooting Guide
3000158-01 Megadyne Mega Power Electrosurgical Generator Operators Manual ~ www.e-ifu.com
3000159-01 Megadyne Mega Power Electrosurgical Generator Service Manual ~ www.e-ifu.com
CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate
CS-SOP-001 - Service and Repair Procedure
ENG-FRM-013, Mega Soft Patient Return Electrode, Service and Repair Form
ENG-WI-035 Mega Power 1000 Packaging Instructions, Service and Repair
ENG-WI-036 Mega Power 1000 Disassembly Instructions, Service and Repair
ENG-WI-037 Mega Power 1000 Assembly Instructions, Service and Repair
ENG-WI-053 Mega Soft Patient Return Electrode Service and Repair Instructions

RA-SOP-012 - Document Management and Record Retention Procedure
QA-SOP-013 - Document Change Order System Procedure

Megadyne will determine statutory and regulatory requirements related to introducing the device to the marketplace. Megadyne will be responsible for all regulatory strategies for submission of the appropriate documentation to ensure products are legally placed into the marketplace.

5 Standards

EN ISO 9001:2015 (ISO 9001:2015 (EQV)), Quality Management Systems - Requirements (ISO 9001:2015)
EN ISO 13485, Medical devices – Quality management systems - Requirements for regulatory purposes
21 CFR Part 820, Quality System Regulation
21 CFR Part 803, Medical Device Reporting
21 CFR Part 210, CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL
21 CFR Part 11, Electronic records; electronic signatures
21 CFR Part 806 Reports of Corrections and Removals
21 CFR Part 7, Enforcement policy
European MDD 93/42/EEC Concerning Medical Devices as amended by 2007/47/EC
SOR/98-282, Medical Device Regulations
Japan MHLW Ministerial Ordinance No.169, 2014 - Medical Device QMS requirements
2002 Law No. 96, Japan Pharmaceuticals Affairs Law
2004 MHLW Ordinance No. 135, Japan Ministerial Ordinance Concerning Post Marketing Safety Standards for Pharmaceuticals, Quasi Drugs, Cosmetics and Medical Devices
2004 MHLW Ordinance No. 136, Japan GQP Ministerial Ordinance
Australia Therapeutic Goods (Medical Devices) Regulations, 2002
EN 60601-1:2006 + A12:2014, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (Equivalent to IEC 60601-1 ed. 3.1)
EN 60601-1-2:2015 (IEC 60601-1-2:2014), Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-2-2:2017 ed. 6.0, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
CSA CAN/CSA-C22.2 NO. 60601-1:14 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition, 2005-12, including amendment 1:2012, with Canadian deviations)
The Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/C
RDC 16/2013 of March 28, 2013, GMP Requirements for Medical Devices and IVDs (Brazil)
ABNT NBR IEC 60601-1:2010 Amd 1: 2016, (Identical to IEC 60601-1 amd.1 Ed. 3.0 b:2012), Medical electrical equipment Part 1: General requirements for basic safety and essential performance (Brazil)

6 Training

**Megadyne Engineering or their authorized representative will provide to service center technicians and/or engineers, the appropriate initial training to properly analyze and/or repair devices. Training will meet the intent of WE001534 and all Megadyne requirements. Ethicon Endo Surgery will communicate the training requirements of WE001534 to Megadyne who will ensure these requirements are covered in the training agenda. Part of the technical training program shall be procedures for product release. The trainer shall train the service center technician/engineer or service center quality assurance associate how to perform product release for the product. Associates will be trained to applicable internal procedures through Compliance Wire.

7 Statistical Techniques

Ethicon Endo Surgery CP0030 will govern the statistical techniques processes that may be used for Megadyne capital equipment. CP0030 does not replace the current Statistical Techniques procedure implemented at Megadyne (QA-SOP-012) of all other processes as defined in the purpose section of QA-SOP-012 (Sampling and Statistical Techniques)

7.1 Sample Size Criteria

NA - Sampling will not be necessary as each device will be serviced and repaired individually. Each device will have complete verification or 100% inspection.

8 Design Verification Strategies and Tools

8.1 Engineering Builds / Pilot(s)

NA - Design Verification will not be necessary as this quality plan addressed service and repair only, not product development.

8.2 Predictive Design Evaluations

NA - Predictive Design Evaluations will not be necessary as this quality plan addressed service and repair only, not product development.

8.3 Predictive Design Targets

NA - Predictive Design Targets will not be necessary as this quality plan addressed service and repair only, not product development.

8.4 Design Verification – Criteria for Success including Reliability (Success Probability) and Confidence Levels (Sampling Risk)

NA - Design Verification will not be necessary as this quality plan addressed service and repair only, not product development.

8.5 Identification of Quality and/or Analysis Tools

- **MD Service & Repair, system tool utilized to create and maintain the service record electronically.
- **Megadyne referenced documents are controlled in Megadyne's document control system. They are made available to the EES Service Center through access to the system.
- EtQ Reliance MDD Nonconformance software, Copyright © 2014 - 2015 EtQ.
- EduNeering ® Compliance Wire System, Enterprise Learning Management System 2017 R2, Version 2.0, to ensure personnel have the competence (education and experience) and training to perform their responsibilities within regulated activities.

8.6 Identification and Validation of Test Methods

Megadyne is responsible for all service and repair training along with providing all controlled documentation for the capturing of service and repair activities. Megadyne documents related to this part are: 3000144-01 Megadyne Mega Power Field Calibration Manual; 3000145-01 Megadyne Mega Power Trouble Shooting Guide; 3000158-01 Megadyne Mega Power Electrosurgical Generator Operators Manual ~ www.e-ifu.com; 3000159-01 Megadyne Mega Power Electrosurgical Generator Service Manual ~ www.e-ifu.com; CS-FRM-034, Mega Power Service Center Repair Form, New Faceplate; ENG-FRM-013,

Mega Soft Patient Return Electrode, Service and Repair Form; ENG-WI-035 Mega Power 1000 Packaging Instructions, Service and Repair; ENG-WI-036 Mega Power 1000 Disassembly Instructions, Service and Repair; ENG-WI-037 Mega Power 1000 Assembly Instructions, Service and Repair; and ENG-WI-053 Mega Soft Patient Return Electrode Service and Repair Instructions. This will be handled through WE001534 and qualifications will be handled per 100584788.

8.7 Delta E Selection Strategy

NA - Delta E Selection Strategy will not be necessary as this quality plan addressed service and repair only, not product development.

9 Reliability

NA - This section does not apply due to product reliability is the responsibility of Megadyne.

10 Design Control

**NA - This section does not apply due to product design control is the responsibility of Megadyne.

11 Document Control

**Documents developed at EES per WE0137 and 100584788 will be reviewed and approved through EES procedures CP0160 and stored in the EES document control system. These documents will follow CP0001.

**Documents developed by Megadyne will be reviewed and approved through Megadyne procedures RA-SOP-012 - Document Management and Record Retention Procedure and QA-SOP-013 – PLM Change Control Document Management Procedure and delivered to EES Service and Repair through the Megadyne Service communication processes per CS-SOP-001.

**Any proposed changes by Megadyne with a service or repair impact will be communicated to EES through CS-SOP-001. No changes shall be implemented by EES prior to the receipt of a documented training, and vice versa for EES generated deliverables where Megadyne is designated a signatory. Review and approval of document changes by Megadyne shall be performed by individual(s) according to QA-SOP-013 PLM Change Control Document Management Procedure and according to CP0160 for EES generated documents.

11.1 Records

**Records retention periods will be per WWRIM Standard RIMS-12. Megadyne has procedures for adherence to the standard within Megadyne controlled records and EES procedure 100095458 is for adherence for EES controlled records. Access will be through the EES document control system and the Megadyne document control system.

12 Process Qualification

12.1 Process Characterization

Process characterization is the responsibility of Megadyne and Ethicon Endo Surgery will perform all servicing activities per Megadyne approved processes and bulletins.

12.2 Delta P Selection Strategy

NA - This section does not apply due to Delta P strategy is the responsibility of Megadyne.

12.3 Component Qualification

Megadyne shall deliver all components used in the service and repair of the product. Parts will be received per WE001150 and inspected and released per WE001369.

12.4 Manufacturing Process Validation

This section has been modified to address the service and repair process validation since manufacturing is not performed.

Process outputs will be verified as outlined within the process specification PR001566 and PR001567. The methodology of setting up the service and repair process in the service center is per WE001534 and the creation of a factbook. The service and repair process validation will be completed through Installation Qualification(s), and Performance Qualification(s) per 100584788 with guidance from CP0198. The center will be using the Service & Repair system for collection and storage of the service record. Megadyne documentation including the service manual for Mega Power™ 1000 Electrosurgical Generator and Mega Soft™ Reusable Patient Return Electrodes will be used in the process of service and analysis.

The process validation plan, including any deviations or assumptions, will be documented in the project protocol PRC086802 and PRC090330, Megadyne Mega Soft Service Validation Summary Report. Requirements for process validation protocols will align with EES Manufacturing Process Validation Procedure CP0198 (Appendix II) and 100584788.

The material specifications for the Megadyne Capital Equipment requirements have been validated in a Performance Qualification during production validation at the original equipment manufacturer. No further actions are required at Ethicon Endo Surgery.

12.5 Production and Process Control

EES will use their own production and process control procedures outlined in PR001566 and PR001567, for the service and repair of Megadyne products. These production and process procedures will be approved at the PR process level. Electrostatic safety controls will be controlled per WE001145. Control of inspection, measuring, and test equipment will be per CP0190. Decontamination control procedures will be per WE001143.

An Intra-Company Quality Agreement (100571196, Quality Agreement EES LLC EES INC Megadyne) per, PR-0000394, has been developed and approved (driven by the Megadyne organization) to define responsibilities and relationships related to supply of product and ongoing lifecycle maintenance. Examples may include design control, product change, complaint handling, supplier quality, post-market surveillance, CAPA decisions, resourcing, field actions, etc. This agreement will include the transition responsibilities during the production stabilization period.

13 Identification and Traceability

Identification:

> Megadyne™ Mega Power™ 1000 Electrosurgical Generator and Megadyne™ Mega Soft™ Reusable Patient Return Electrodes, will be tracked by serial number.

Traceability:

Service and repair activities will be documented on the forms that have been created and will be attached on Service & Repair system. Originals will be maintained and filed, after quality has reviewed for accuracy and attached to the database. A listing of forms can be found in PR001566 and PR001567.

14 Labeling and Package Control

EES will develop box labeling according to procedure WE001147 using Avery labels or equivalent. All packaging for the Megadyne™ Mega Power™ 1000 Electrosurgical Generator and Megadyne™ Mega Soft™ Reusable Patient Return Electrodes, are specified by Megadyne will be controlled as part numbers. Labeling and packaging will be verified to EES procedures WE001150 and WE001369.

15 Purchasing Controls

Suppliers, contractors, and consultants will be on EES approved supplier list as customer or Megadyne authorized suppliers per 100583095. Megadyne will be responsible for all supplier quality management deliverables.

Sub-assembly and assembly testing will be accomplished by using appropriate Megadyne quality systems. Qualification will be challenged as part of the Verification Protocol(s). Product serviceability by EES shall be accomplished through the Fact Book process WE001534.

16 Acceptance Activities

EES will use their own receiving and final acceptance processes. (WE001142; WE001150; WE001302, and WE001369) EES will maintain objective evidence that acceptance was performed.

17 Non-conforming Product

All products found to be nonconforming will be quarantined. A non-conformity report will be generated within the Megadyne instance of EtQ Reliance MDD Nonconformance software. Disposition will be directed through this process as outlined by 100254122. EES nonconforming processes will generate a non-conformity report per PR-0000256.

18 Corrective and Preventive Action

CAPA will not be the responsibility of EES as it relates to the product but will as it relate to service and repair. Megadyne will utilize the CAPA process, which is governed by PR575-001. Post-launch, production, and complaint data will be monitored as input into the CAPA process according to PR-0000368. CAPA will be the responsibility of EES as it relates to EES service and repair processes. EES will utilize the CAPA process, which is governed by PR575-001.

19 Handling, Storage, Distribution and Installation

EES will follow the Handling, Storage, Distribution and Installation instructions identified in CP000407 and WE001147.

20 Servicing

Servicing will be through the EES service center. Servicing activities are certified per the EES Service and Repair fact book process WE001534 and will follow the processes outlined in PR001566 and PR001567.

21 Complaint Handling

Complaint handling will be per 100538251. Device analysis will be handled by the EES service centers per PR001566 and PR001567. Data will be uploaded into the Service & Repair service database and reviewed according to the Megadyne complaint management system.

22 Appendices

NA

SCN0057675 Revision History

Date	What Changed	Reason for Change (Why?)
02/07/20	Added clarification in Section 6 Training for Megadyne and EES responsibilities. Added "MD" to Section 8.5. Removed "Master Control" title from Section 8.5. Replaced Epiceneter and Adaptiv in Section 11.0 and 11.1 with "the EES document control system". Removed reference to "SharePoint/Office 365 web site" in Section 8.5 and 11.1. Changed document title for QA-SOP-013 in section 11. Corrected error for "reliability" to "design control" in Section 10.	Training section need more information identifying how Megadyne would integrate EES training requirements into product training. Clarified the service and repair system that creates records. Removed the name of the Megadyne document control system making it to be more generic which allow for system changes without needing to update this agreement every time. Made the EES document control system more generic which allow for system changes without needing to update this agreement every time. Corrected document titles. EES will no longer use a SharePoint site for Megadyne controlled documents. Changed quality system signature name. Removed obsolete document QA-ICQA-0001, 3-Way ICQA EES LLC EES INC Megadyne from the reference documents and the body of the plan. Added (100571196, Quality Agreement EES LLC EES INC Megadyne) in section 12.5 as clarification.
11/11/19	Corrected validation document number in Ethicon Document section and in Section 12.4. added "Master Control" to section 8.5 referencing Megadyne's document management system. Updated approver names and titles.	Update the document to reflect current validation documentation and clarify naming for Megadyne's document management system. Updated approver names and titles.
10/02/18	Added product codes: 1000, Megadyne™ Mega Power™ 1000 Electrosurgical Generator 800; 800S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – Mega 2000 0830; 0830S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft 0835; 0835S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft Dual 0840; 0840S, Megadyne™ Mega	New products have been introduced into the service and repair processes within the service center.

	Soft™ Reusable Patient Return Electrodes – MegaSoft Pediatric 0845; 0845S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft Universal 0846; 0846S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft Universal Dual 0847; 0847S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft Universal Plus 0848; 0848S, Megadyne™ Mega Soft™ Reusable Patient Return Electrodes – MegaSoft Universal Dual Sample	