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# **Annual Quality Review Meeting Service Call Center - Italy**

**Date: 22 – 04 - 2020**

**Ethicon Endo-Surgery**

# Attendees

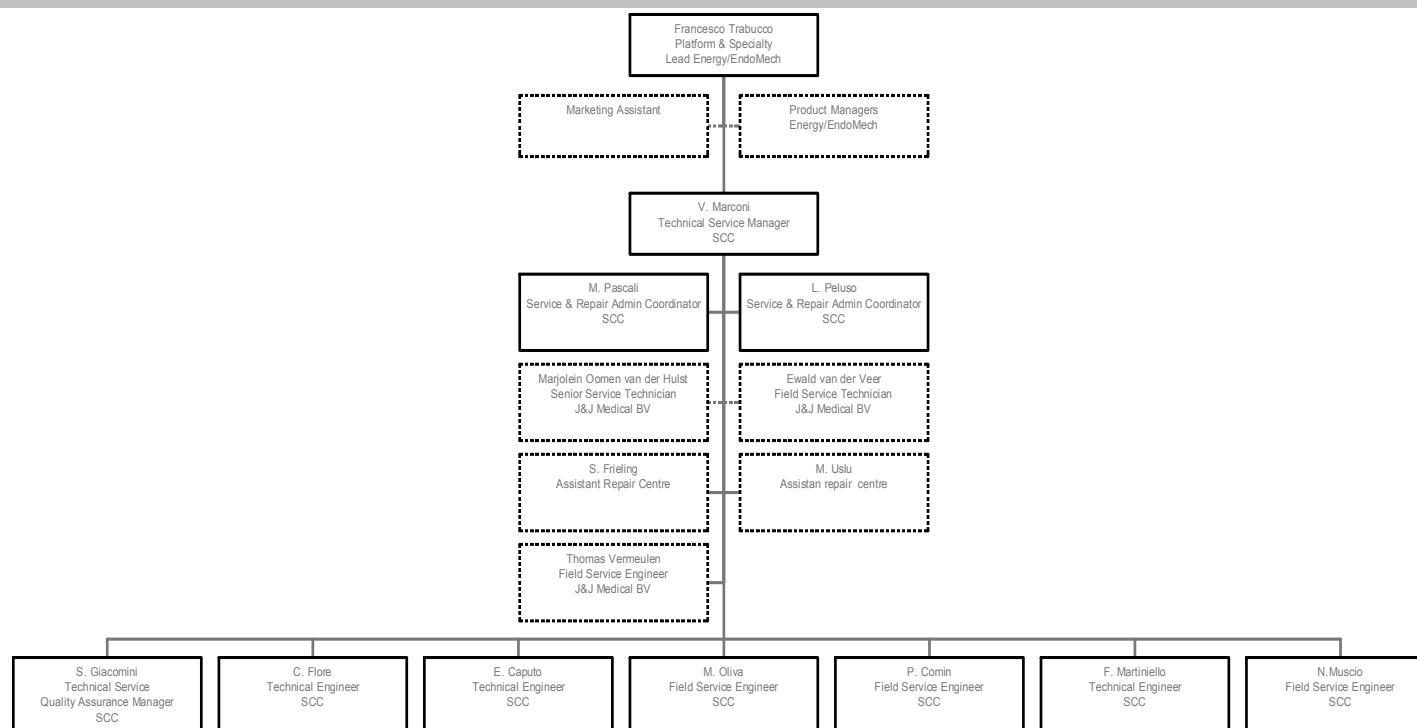
| Name               | Title                         |
|--------------------|-------------------------------|
| Valerio Marconi    | Technical Service Manager     |
| Stefania Giacomini | Technical Service QA Manager  |
| Francesco Trabucco | Platform & Specialty Lead     |
| Shannon Gillespie  | International Service Manager |
| Robert Peters      | Service Quality Lead          |
| James Swords       | WTCS-Coordinator              |
| James Terry        | Product Release Technician    |

# Agenda

- Organizational changes
- Follow-up items from previous quality review
- Significant changes in Quality System
- Average monthly service volume during last 12 months
- Service training results
- Product quality review
- Scorecard Metrics
- Management Review Summary
- Compliance Update
- Certifications
- Records Review for destruction
- General discussion

# Organizational Changes

# Organizational changes



# Organizational changes

| Please answer the following:  | Yes or No | Comments   |
|---|-----------|--|
| Have there been any changes in the org chart since the last review?                                     | Yes       | New Field Service Engineer was hired.<br>Two more Dutch engineers were trained on GEN11 field PM |
| Have there been changes in site location; expansion; or facility layout?                                | No        | N/A  |
| Have there been significant changes that adversely affect EES products, processes, or product release ? | No        | N/A.   |

# Follow-up Items from Previous Review



# Follow –up Items from previous quality review

**Below is a list of follow up action items as a result of the Italy 2019 Annual Business Review:**

|   |  |
|---|--|
| Send to Italy Team copy of process specification and forms for Megadyne 1000 power generator. Including WO# for review. | Responsible Party: James Terry<br>Due date: 11st June, 2019<br>Actions completed on 5 <sup>th</sup> June, 2019: – James Terry sent an email to Stefania Giacomini and Valerio Marconi including documents. <b>Completed will be documented in DOC000665 Rev W.</b>           |
| Send training records for Christine Flore.  | Responsible Party: Stefania Giacomini<br>Due date: 17th June, 2019<br>Actions completed on 5 <sup>th</sup> June, 2019: – Stefania Giacomini sent an email to James Terry and Robert Peters including the PDF record. <b>Completed will be documented in DOC000665 Rev W.</b> |
| Send Gen 04 electrical safety records for GN4051712-WO#-23750-GN4068577-WO#-23491                                       | Responsible Party: Stefania Giacomini<br>Due date: 17th June, 2019<br>Actions completed on 5 <sup>th</sup> June, 2019: – Stefania Giacomini sent an email to James Terry and Robert Peters including the PDF record. <b>Completed will be documented in DOC000665 Rev W.</b> |
| Send New Lay Out for platform changes   | Responsible Party: Stefania Giacomini<br>Due date: 17th June, 2019<br>Actions completed on 11st June, 2019: – Stefania Giacomini sent an email to Terry James and Robert Peters including the new layout. <b>Completed will be documented in DOC000665 Rev W.</b>            |

# Significant Changes in Quality System

# Significant Changes in Quality System

| Please answer the following:   | Yes or No | Comments   |
|--|-----------|--|
| Has there been any changes significant changes to the Quality System in the last year? | Yes       | Service New product<br>Change to quality system based on recent audits<br>Spare parts tracking |

- Fully authorization for servicing and repair FMS Vue II products
- Fully implementation in MD S&R for spare parts tracking (availability of spare parts)
- Based on a recent JJRC audit, the management of measurement equipment used by field engineers in Nederland's

# Average Monthly Service Volume During the Last 12 Months

## Average Monthly EES Service volume during last 12 months

Total units in 12 months = 80.75 units/month (01-01-2019-31-12-2019). This means Italy will remain a medium volume service center.

| Product Name            | # of products serviced between<br><u>01-01-2019 TO 31-12-2019</u> |
|-------------------------|---|
| GEN11                   | 960   |
| GEN04                   | 7   |
| RF60                    | 0   |
| MegaPower Generator     | 2   |
| MegaVac Smoke Evaluator | 0   |
| MegaSoft Pads           | N/A   |
| MiniVac                 | N/A   |

# Service Training Results

# Service Training Results for Newly Trained and Ongoing Personnel

Document New/Ongoing/Re-Certification training in chart for each product here.

| Training Title/Type          | Technician            | Trainer (Person or System) | Training Date |
|------------------------------|-----------------------|----------------------------|---------------|
| GEN 11 Recertification       | Valerio Marconi       | F.Trabucco                 | 10-dic-19     |
| GEN 11 Recertification       | Stefania Giacomini    | F.Trabucco                 | 09-nov-19     |
| GEN 11 Recertification       | Massimiliano Oliva    | F.Trabucco                 | 28-nov-19     |
| GEN 11 Recertification       | Emanuela Caputo       | F.Trabucco                 | 02-dic-19     |
| GEN 11 Recertification       | Paolo Comin           | F.Trabucco                 | 06-dic-19     |
| GEN 11 Recertification       | Francesca Martiniello | F.Trabucco                 | 11-dic-19     |
| GEN 11 Recertification       | Nicola Muscio         | F.Trabucco                 | 04-dic-19     |
| GEN 11 Recertification       | Christian Flore       | F.Trabucco                 | 06-dic-19     |
| GEN04 Recertification        | Valerio Marconi       | F.Trabucco                 | 10-dic-19     |
| GEN04 Recertification        | Stefania Giacomini    | F.Trabucco                 | 09-dic-19     |
| GEN04 Recertification        | Massimiliano Oliva    | F.Trabucco                 | 28-nov-19     |
| GEN04 Recertification        | Emanuela Caputo       | F.Trabucco                 | 02-dic-19     |
| GEN04 Recertification        | Paolo Comin           | F.Trabucco                 | 06-dic-19     |
| RF60 Recertification         | Valerio Marconi       | F.Trabucco                 | 10-dic-19     |
| RF60 Recertification         | Stefania Giacomini    | F.Trabucco                 | 09-dic-19     |
| RF60 Recertification         | Massimiliano Oliva    | F.Trabucco                 | 28-nov-19     |
| RF60 Recertification         | Emanuela Caputo       | F.Trabucco                 | 02-dic-19     |
| RF60 Recertification         | Paolo Comin           | F.Trabucco                 | 06-dic-19     |
| Complaint Awareness          | Valerio Marconi       | F.Trabucco                 | 10-dic-19     |
| Complaint Awareness          | Stefania Giacomini    | F.Trabucco                 | 09-dic-19     |
| Complaint Awareness          | Massimiliano Oliva    | F.Trabucco                 | 28-nov-19     |
| Complaint Awareness          | Emanuela Caputo       | F.Trabucco                 | 02-dic-19     |
| Complaint Awareness          | Paolo Comin           | F.Trabucco                 | 06-dic-19     |
| Complaint Awareness          | Francesca Martiniello | F.Trabucco                 | 10-dic-19     |
| Complaint Awareness          | Nicola Muscio         | F.Trabucco                 | 04-dic-19     |
| Complaint Awareness          | Christian Flore       | F.Trabucco                 | 06-dic-19     |
| Complaint Awareness          | Michela Pascali       | F.Trabucco                 | 02-dic-19     |
| Complaint Awareness          | Leonardo Peluso       | F.Trabucco                 | 02-dic-19     |
| GEN11 certification          | Nicola Muscio         | E. Caputo                  | 02-ago-19     |
| GEN11 Field PM certification | Suzanne Frieling      | V.Marconi                  | 03-oct-19     |
| GEN11 Field PM certification | Muhammet Uslu         | V.Marconi                  | 03-oct-19     |

# Service Training Results for Newly Trained and Ongoing Personnel

| Product Name            | Training the Trainer Name(s)                                      |
|-------------------------|---|
| GEN11                   | Valerio Marconi, Emanuela Caputo, Paolo Comin, Massimiliano Oliva |
| GEN04                   | Stefania Giacomini, Emanuela Caputo, Paolo Comin, Valerio Marconi |
| RF60                    | Stefania Giacomini, Emanuela Caputo                               |
| MegaPower Generator     | Massimiliano Oliva  |
| MegaVac Smoke Evaluator | Massimiliano Oliva  |
| MegaSoft Pads           | N/A   |
| MiniVac                 | N/A   |



# Product Quality Review

# Product Quality Review

| Please answer the following:  | Yes or No | Comments  |
|---|-----------|---|
| Have there been any non-conformances for product or systems?  | Yes       | A NC was detected during JJRC Audit (23-25- 10-2019)  |
| Have there been any corrective/preventive actions identified in product or processes since the previous review? | Yes       | 3 Corrective actions and 2 Preventive actions were opened following the JJRC NC:<br>CPA 1687700<br>CPA 1687704<br>CPA 1687713<br>CPA 1687716<br>CPA in progress<br>1 Quality Issue (1547634) was opened and correction 1564641 was completed on 17-10- 2019 related to a recommendation arisen during Internal audit (20 - 06-2019) |
| Has CAPA (Corrective And Preventive Actions) been determined as effective?                                      | Yes       | The effectiveness of CAPA related to NC of JJERC audit will be checked at the end of 31-09-2020.  |

# Product Quality Review

A sample of twenty service records was requested per sampling plan ANSI/ASQC Z1.4 Normal Level I AQL = 0.65 – Accept 0; Reject 1

17 GEN 11 Records

2 GEN 04 Records

1 Mega power 1000

# Product Quality Review

| Service Bulletin # | Product   | Service Bulletin Release Date | Implementation Date |
|--------------------|---|-------------------------------|---------------------|
| SB 19-001          | Release Megadyne CS-FRM-034 Rev 005 with updated Parts list     | 16-08-2019                    | 3-09-2019           |
| SB 19-004          | Megadyne Field Action - ESU Output Connection Instruction Label | 10-09-2019                    | 16-10-2019          |
| SB 19-005          | Mega Power Incorrect Authorized Rep on Rear Panel Label         | 30-01-2020                    | 31-01-2020          |

# Scorecard Metrics

# Scorecard Metric Review

**Repair cycle time overall goal: 7 days**

**List repair cycle time overall goal above.**

|                         |  |
|-------------------------|--|
| GEN11                   | List results for GEN11 here. <a href="#">3</a> days.   |
| GEN04                   | List results for GEN04 here. <a href="#">2</a> days.   |
| RF60                    | List results for RF60 here. <a href="#">No RF60 serviced during 2019</a>                                       |
| MegaPower Generator     | List results for MegaPower Generator here. <a href="#">12</a> days   |
| MegaVac Smoke Evaluator | List results for MagaVac Smoke Evaluator here. <a href="#">No MegaVac Smoke Evacuator serviced during 2019</a> |
| MegaSoft Pads           | List results for the name of the train the trainer for MegaSoft Pads here. <a href="#">N/A</a>                 |
| MiniVac                 | List results for MiniVac here. <a href="#">N/A</a>   |

# Scorecard Metric Review

| Metric  | Results                           |
|---|-----------------------------------|
| Repeat service < 90 days, goal: $\leq 1$  | Result = 0.1%                     |
| Number of service complaints, goal: $\leq 1$  | Result = 0                        |
| Customer Satisfaction goal: ____  | Result = 4.9 (ISO certified only) |
| Discuss timeliness for Global Scorecard reports.  | Result = 100%                     |
| Discuss timeliness for Service Activity Reports   | Result = 100%                     |
| Field efficacy (% of serviced devices vs planned services)                                  | Result=97.3%                      |
| Fielad Accuracy (% of devices serviced within 1 year + 3 month from previous check)         | Result=96.7%                      |
| Volume 1: Number of serviced devices covered by service contract vs contract installed base | Result=100%                       |
| Volume 2: Number of company serviced devices vs installed base                              | Result=78.8%                      |

# Management Review Summary



# Management Review Summary (1)

## List Results and Actions between 04-06-2019 to 22-04-2020 from Management Reviews:

|                                |   |
|--------------------------------|---|
| Date of last management review | <a href="#">10-03-2020</a>  |
| Accomplishments?               | <ul style="list-style-type: none"> <li>- New agreement signed with other Countries to support them with service and repair activities: Poland, France, Spain, Portugal, Belgium, Greece and Cyprus (including Megadyne for last 2 Countries)</li> <li>- Completed authorization for service and repair activities on FMS Vue II</li> <li>- New field service structure (3 field technicians) to cover needs of service both for Mitek and Ethicon</li> <li>- 32 Pure Vue installed on site with the support of field service engineers</li> <li>- The operativity of work order processing has been completely switched to digital</li> </ul> |
| Business plan goals?           | <ul style="list-style-type: none"> <li>- Complete Mitek service and repair authorization (Micro HP, Pure Vue)</li> <li>- Complete Megadyne service and repair authorization for new platform (Winston and GoldenGate)</li> <li>- Plan Wave 2 of EMEA project in order to include Mitek platform</li> <li>- Implement field processes also for Germany like Nederland model</li> <li>- Plan new layout for depot service center if needed</li> <li>- Switch ancillaries processes of service (e.g. Service contracts, tools, etc) in MD S&amp;R</li> </ul>   |

# Management Review Summary (2)

## List Results and Actions between 04-06-2019 to 22-04-2020 from Management Reviews:

|  |  |
|--|--|
| Action items from the management review related to or affecting service? | No action related to GEN11<br>Only 1 Quality Issue managed and completed related to Mitek cycle time   |
| Any significant Service Center internal audit trends?                    | No   |
| Discuss any corrective and/or preventive actions implemented.            | List any actions, if applicable.<br><b>3 Corrective actions and 2 Preventive actions were opened following the JJERC NC:</b><br><b>CPA 1687700</b><br><b>CPA 1687704</b><br><b>CPA 1687713</b><br><b>CPA 1687716</b><br><b>CPA in progress</b><br><b>1 Quality Issue (1547634) was opened and correction 1564641 was completed on 17 -10-2019 related to a recommendation arisen during Internal audit (20 June, 2019)</b><br>Was CAPA determined as effective? Yes___ No___ N/A <u>X</u><br>The effectiveness of CAPA will be verified at the end of 31-09-2020 |
| Other ?  | None   |

# Compliance Update

# Compliance Update

## Include Internal and Third Party:

- Any audits since last review – Yes ☒ No ☐
  - Internal audit (20-06-2019)
    - An internal audit was conducted by Alessandra Tabanelli. There were 2 recommendations: one related to description of compliance results on service reports and the other one related to the opportunity to implement IT tool for equipment. The Correction for the first recommendation was completed on 17-10-2019 (Correction 1564641). For the second one non correction was implemented since NC was not found.
  - Third Party audit (15-16 -07-2019)
    - Successful Third Party Audit held by the notified body Certiquality on 15-16 -07-2019 to confirm the conformity to ISO 9001:2015 and ISO 13485: 2016 standards. No recommendation nor NC were detected.
  - JJRC Audit (23-25 -10-2019)
    - A J&J Enterprise Regulatory & Compliance audit was held on 23-25-10- 2019. There was 1 NC related to the management of calibration certificates provided by Netherland affiliate. 3 Corrective actions and 2 preventive actions were opened. The effectiveness will be verified in 31-10-2020.
- Any scheduled future audits – Yes ☐ No ☒

# Certifications

# Certifications

Please answer the following:

Are you certified by any Notified Body or Accreditation group?

Yes or No

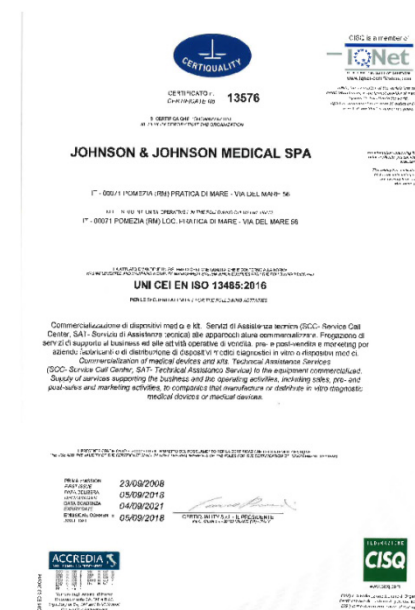
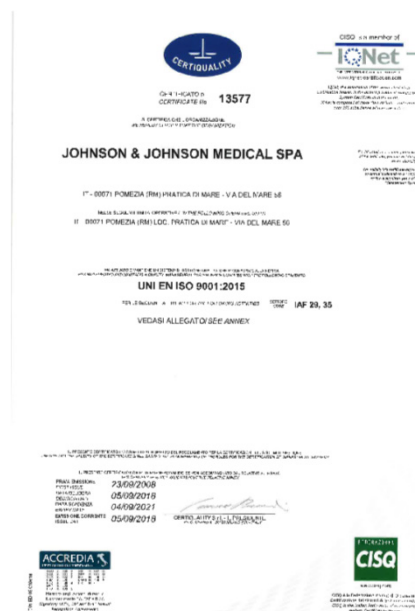
Yes

Comments

See below.

Provide copies of latest certifications

- ISO 9001:2015 certificate
- ISO 13485:2016 certificate



# Records Review for Destruction

## Records Review for Destruction

- GEN32 records that are due for destruction are stored in a manner that will require holding on to them until destruction in 2023 along with GEN04 per Italy's record retention.



# General Discussion

# General

General information that additionally effects your business

- Robotics (news ?)
- Suggestion: give guidelines to all service centers on how to complete data fields within the Work Order in MD S&R

# Action Items

## Below is a list of follow up action items as a result of the Italy 2020 Annual Business Review:

|   |  |
|---|--|
| Ensure functional testing is captured or documented and uploaded into MDS&R for all records | Responsible Party: Italy Service Team<br>Due date: End of Q4 2020<br>Actions completed on (02-09-2020): – New Service Report is on the way to be made effective on 13th July we received final feedback from James Terry, we expect to implement it by the end of august – <b>Complete</b> .   |
| Ensure IMT dates are captured or documented and uploaded into MDS&R for all records         | Responsible Party: Italy Service Team<br>Due date: End of Q4 2020<br>Actions completed on (02-09-2020): – New Service Report is on the way to be made effective on 13th July we received final feedback from James Terry, we expect to implement it by the end of august – <b>Complete</b> .   |
| Provide 7 electrical safety test documentation from sample of service records               | Responsible Party: Italy Service Team<br>Due date: 22-05-2020<br>Actions completed on (23-4-2020): – Stefania Giacomini supplied an e-mail with 7 requested electrical safety test. All records were good and will be attached as evidence to <b>DOC000665 Rev W. Completed</b> . The records will need to be attached to the service database as required by action “Ensure functional testing is captured or documented and uploaded into MDS&R for all records” |
| Send recertification documentation to Italy service team for Megadyne                       | Responsible Party: Shannon Gillespie/Jason Stivers/Janet Holt<br>Due date: 22-05-2020<br>Actions completed on (22-04-2020; 06-05-2020): – Janet provided recertification documentation to Italy Service team. Email will be used as evidence of this action. <b>Complete</b>   |

# Action Items - Continued

**Below is a list of follow up action items as a result of the Italy 2020 Annual Business Review:**

|   |   |
|---|---|
| Italy team to provide a breakdown of service volumes between regions of Italy and Netherlands   | Responsible Party: Italy Service Team<br>Due date: End of Q4 2020<br>Actions completed on (date): – 2019 Breakdown communicated by Stefania (email will be attached as evidence to <b>DOC000665 Rev W</b> ). We are communicating the breakdown on a monthly basis since June 2020 when submitting Global Scorecard. – <b>Complete.</b> |
| Italy team to update output verification form to capture steps related to final inspection test results as defined from the service manual. | Responsible Party: Italy Service Team<br>Due date: End of Q4 2020<br>Actions completed on (02-09-2020): – New Service Report is on the way to be made effective on 13th July we received final feedback from James Terry, we expect to implement it by the end of august – <b>Complete.</b>   |

# On-site Audit Required for Further Risk Assessment

| EES to complete | Yes or No | Comments |
|-----------------|-----------|----------|
| Audit Required? | No        | N/A      |

Next quality review meeting [31-12-2021](#).