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Johnson & Johnson MEDICAL DEVICES COMPANIES

Annual Quality Review Meeting

(Johnson & Johnson KK, Japan Service Center, Sukagawa City, Fukushima Pref.)

Date:(25– 08 - 2020)

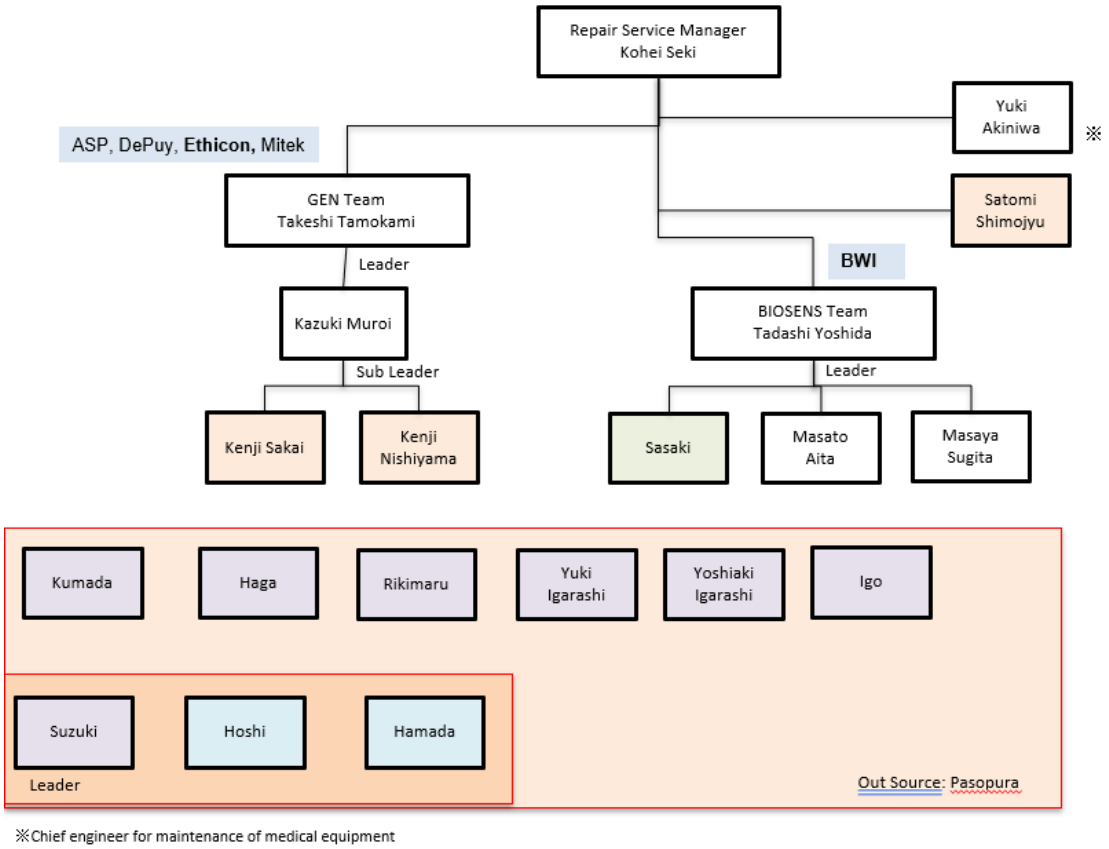
Ethicon Endo-Surgery

Name	Title
Kohei Seki	Repair Service Manager
Yuki Akiniwa	Chief Engineer
Kazuki Muroi	Technical Group
Takeshi Tamokami	Technical Group
Shannon Gillespie	International Service Manager
James Swords	WTCS-Coordinator II
James Terry	Product Release Technician IV
Robert Peters	Service Quality Lead

Agenda
Organization Changes
Follow Ups from previous review
Service and Quality Agreements Update
Significant changes in Quality System
Review of service volume since the previous review
Review of Service Metrics
Service training results
Product quality review (Service Database/Service reports)
Management Review Summary
Compliance Update
Certifications
Project Review
Records Review for destruction
General discussion

Organizational Changes

Organizational changes



※Chief engineer for maintenance of medical equipment

Organizational changes

Please answer the following:	Yes or No	Comments
Have there been any changes in the org chart since the last review?	Yes	Masato Aita and Tomomi Igo joined.
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 ?	Yes	PM & CM of MegaPower1000&MegaSoft started.

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 Japan 2019 Annual Business Review:

EES to provide to JAPAN team information and contacts for • LX1##, LX2##, LC3##, LC4##, Liga Clip Applier.	Responsible Party: Robert Peters Due date: 20-11-2019 Actions completed on 20-11-2019): Robert provided the information to the Japan team in an e-mail evidence can be found on DOC020920 Rev G
EES to provide to JAPAN team information and contacts for Handpiece(HP) Receptacle Connection failure causes cable communication error between Gen 11 and HP are increasing	Responsible Party: Robert Peters Due date: 20-11-2019 Actions completed on 20-11-2019): Robert provided the information to the Japan team in an e-mail evidence can be found on DOC020920 Rev G
Japan team to provide confirmation of SB 17-0003.	Responsible Party: Yuli Akiniwa Due date: 26-11-2019 Actions completed on (26-11-2019): Yuki provided the information to EES team in an e-mail evidence can be found on DOC020920 Rev G
Japan team to provide Global scorecard for months missing 2018.	Responsible Party: Yuli Akiniwa Due date: 31-12-2019 Actions completed on (31-12-2019): Yuki provided the information to EES team in an e-mail evidence can be found on DOC020920 Rev G
Japan team to provide SR#.225002 teat data for review possible traveler for decontamination for all files.	Responsible Party: Yuli Akiniwa Due date: 26-11-2019 Actions completed on (26-11-2019): Documented in the service file review. Can be found on DOC020920 Rev G

Service and Quality Agreements Update

Service and Quality Agreements Update

	Service Agreement	Inter-company Quality Agreement
Is the current agreement still applicable today?	01-09-2019 Service Operating Agreement	01-12-2019
	01-03-2020 Amendment to Agreement	

All agreements are current with no revisions necessary at this time.

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	Windchill implementation since 01-04-2020

Review of Service Volume Since the Previous Review

Service volume since the last review

There were 534 units total between 01-08-2019 to 31-07-2020, representing an Average 28.10 units serviced per month. This means J&J Medical KK will remain a medium volume service center.

Product Name	# of products serviced between 01-08-2019 TO 31-07-2020 Your Service Center data here	# of products serviced between 01-08-2019 TO 31-07-2020 3rd Party Suppliers/Distributors data here	# of products serviced between 01-08-2019 TO 31-07-2020 FSE's data here
GEN11	448	0	0
GEN04	23	0	0
RF60	0	0	0
MegaPower Generator	35	0	0
MegaVac Smoke Evaluator	0	0	0
MegaSoft Pads	28	0	0
MiniVac	0	0	0

Review of Service Metrics

Service Metric Review

Repair cycle time overall goal: 10 days **List repair cycle time overall goal above.**	
GEN11	5.5 days
GEN04	4.6 days
RF60	N/A
MegaPower Generator	4.0 days
MegaVac Smoke Evaluator	N/A
MegaSoft Pads	39.6 days
MiniVac	N/A

Metric	**Results**
Repeat service < 90 days, goal: ≤1	Result = 7
Number of service complaints, goal: ≤1	Result = 1
Customer Satisfaction goal: _2.0%__	Result = 1.64% (ISO certified only)
Discuss timeliness for Global Scorecard reports.	Result = 100%
Discuss timeliness for Service Activity Reports	Result = 100%
Any additional metrics tracked (If service center tracks additional items)	N/A

Service Training Results

Service Training Results for Newly Trained and Ongoing Personnel

Training Title/Type	Technician	Trainer	Training Date
RF60 Recertification	Kenji Nishiyama	Kohei Seki	(18-11-2020)
GEN04	Yuki Akiniwa Kenji Nishiyama	Kohei Seki	(18-11-2020)
GEN 11 Recertification	Yuki Akiniwa Kenji Nishiyama Kazuki Muroi Aimi Haga Kyoko Rikimaru Michiru Hoshi	Kohei Seki	(18-11-2020)
Megadyne Recertification	Kenji Nishiyama Kenji Sakai	Kohei Seki	(25-12-2019)
ISO Training	N/A – See slide 29	N/A – See slide 29	N/A – See slide 29
Complaint Awareness	Yuki Akiniwa Kenji Nishiyama Kazuki Muroi Aimi Haga Kyoko Rikimaru Michiru Hoshi	Kohei Seki	(18-11-2019)

Service Training Results for Newly Trained and Ongoing Personnel

Product Name	Training the Trainer Name(s)
GEN11	Yuki Akiniwa
GEN04	Yuki Akiniwa
RF60	Kenji Nishiyama
MegaPower Generator	Kohei Seki
MegaVac Smoke Evaluator	N/A
MegaSoft Pads	Kohei Seki
MiniVac	N/A

Product Quality Review (Service Database/Service reports)

Product Quality Review

Please answer the following:	Yes or No	Comments
Have the been any non-conformances for product or systems?	Yes	We had NC that quote, and actual service were not same.
Have there been any corrective/preventive actions identified in product or processes since the previous review?	Yes	Process needed to be evaluated and then change the process when/who check
Has CAPA (Corrective And Preventive Actions) been determined as effective?	Yes	NC closed in 30-07-2020 and assume no issue found since then.

Microsoft Word Document

Product Quality Review

A sample of Twenty (20) records were requested per sampling plan, ANSI/ASQC Z1.4 Normal Level I AQL = 0.65 Accept 0: Reject 1 Inspection.

17- GEN11 records

2 - GEN04 records

1 –Megapower 1000

2 – Megapads (see action item slide)

Product Quality Review

Service Bulletin #	Product	Service Bulletin Release Date	Implementation Date
SB 20-003	GEN11	05/05/2020	Not yet, under implementation

Management Review Summary

Management Review Summary

List Results and Actions on 21-02-2020 from Management Reviews:	
Date of last management review	21-02-2020
Accomplishments?	There is no service complaint.
Business plan goals?	There is no service impact.
Action items from the management review related to or affecting service?	GEN11 target was not achieved so it needs to improve, but we enhance 3rd Party PM and CM, it should be improved from Autumn
Any significant Service Center internal audit trends?	There is no significant internal audit trends.
Discuss any corrective and/or preventive actions implemented.	Was CAPA determined as effective? Yes___ No___ N/A X
Other ?	N/A

Compliance Update

Compliance Update

Include Internal and Third Party:

- Any audits since last review – Yes X No
  - "Successful J&J compliance audit was conducted on 11- 2019 by Fukui, Katsumata, Ota. There were 0 findings related to service and repair.
  - Any scheduled future audits – Yes X No

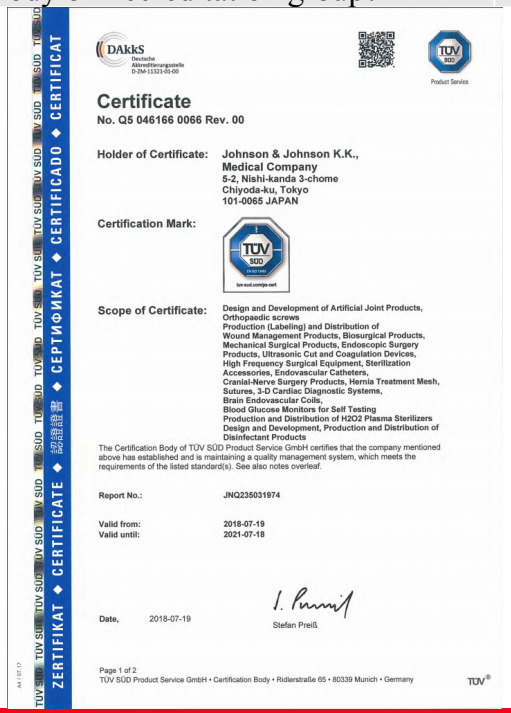
Internal Audit will be conducted in 09- 2020

ISO13485 conducted on 12-08-2020

Certifications

Certifications

Please answer the following:	Yes or No	Comments
Are you certified by any Notified Body or Accreditation group?	Yes	TUV SDU Japan



DAkkS Deutsche Akkreditierungsstelle D-ZM-11323-01-00

TÜV SÜD Product Service

Certificate
No. Q5 046166 0066 Rev. 00

Holder of Certificate: Johnson & Johnson K.K.,
Medical Company
5-2, Nishi-kanda 3-chome
Chiyoda-ku, Tokyo
101-0065 JAPAN

Certification Mark:

Scope of Certificate: Design and Development of Artificial Joint Products, Orthopaedic screws
Production (Labeling) and Distribution of Wound Management Products, Biosurgical Products, Mechanical Surgical Products, Endoscopic Surgery Products, Ultrasonic Cut and Coagulation Devices, High Frequency Surgical Equipment, Sterilization Accessories, Endovascular Catheters, Cranial-Nerve Surgery Products, Hernia Treatment Mesh, Sutures, 3-D Cardiac Diagnostic Systems, Brain Endovascular Coils, Blood Glucose Monitors for Self Testing
Production and Distribution of H2O2 Plasma Sterilizers
Design and Development, Production and Distribution of Disinfectant Products

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: JNQ235031974

Valid from: 2018-07-19
Valid until: 2021-07-18

Date, 2018-07-19

Stefan Preiß

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ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT 認証書

DAkkS Deutsche Akkreditierungsstelle D-ZM-11323-01-00

TÜV SÜD Product Service

Certificate
No. Q5 046166 0066 Rev. 00

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Johnson & Johnson K.K., Medical Company Sukagawa Plant
1 Meotozaka, Ohkanbara, Sukagawa City, Fukushima, 962-8501 JAPAN

Johnson & Johnson K.K., Medical Company
5-2, Nishi-kanda 3-chome, Chiyoda-ku, Tokyo, 101-0065 JAPAN

End of Certificate

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Project Overview

Project Overview

Please answer the following:	Product	Date
Any projects in place to include additional service for new products?	Winston (MES1)	Tentative service center readiness date: Q32020
	Golden Gate (MEGEN1)	Tentative service center readiness date: Q42021

Records Review for Destruction

Records Review for Destruction

Japan was approved for servicing the following devices:

RF60 – November 2009

GEN04 – July 2002

GEN11 – September 2012

Record Destruction begins:

RF60/GEN04 – January of 2029

GEN11 – January of TBD

No records are due for destruction at this moment.

General Discussion

General

- N/A

Action Items

Below is a list of follow up action items as a result of the Japan 2020 Annual Business Review:	
EES to review two service records for the Megasoft Pads.	Responsible Party: James Terry Due date: 11-09-2020 Actions completed on (01-09-2020): – Sent e-mail with two record reviewed. Work order 458222_ SN_ 187125038 & work order 454920_ SN_ 187125046. The information was documented correctly in MDS& R and all test data was attached all other requirements were met per MDS&R. Evidence can be found on DOC020920 Rev H
EES to provide Japan Team with red-line copy of service manual updated in conjunction with SB20-0003	Responsible Party: James Terry Due date: 11-09-2020 Actions completed on (01-09-2020): – Sent e-mail with the information of the changes to the service manual. Evidence can be found on DOC020920 Rev H
EES to provide Japan Team with examples of work order records for review with requirements and recommendations.	Responsible Party: James Terry Due date: 11-09-2020 Actions completed on (01-09-2020): – Sent e-mail with the information examples of work order records for review with requirements and recommendations. Evidence can be found on DOC020920 Rev H

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.