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Revision History for 100645630

Summary of Changes	
Revision No.	Description of Change
5	Chinese translation only. No content changes.
4	Clerical change to include document number and revision in footer.
3	Adding Codman, Pulsar, Neuravi, Depuy and Synthes to the scope per PR-0000089 Franchise Procedure for Validation (Shared). Revised Section 2 to change the word “Does” with “Can”, and add N/A boxes in Comments column. Revised Section 3 to clarify instructions. Revised Section 4 to add “provide rationale below” and “Reason for Process Verification”. Revised Section 5 to add N/A box to question 2, change the word “does” with “can”, add a second question to item 11, and add “process” to verification study to item 9, 10, 11 and 12.
2	Clerical change to include Portuguese and German translations.
1	Initial release for ETH/CSS (Shared) in collaboration with Global Orthopedics as OneMD.

This form supports PR-0000089 Franchise Procedure for Validation (Shared).

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1. Description of change

Description of proposed change	*Introduction of the Service Evaluation Process for the Megadyne Mega Soft Patient Return Electrode (Mega Soft), Product Codes: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S to International Service Centers.*
Reason for change	*Validation of the Service Process for the Megadyne Mega Soft Patient Return Electrode, Product Codes: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S to International Service Centers to support evaluation of the Mega Soft in markets outside of the United States by Johnson and Johnson-qualified centers.*
Product/Site impacted	*Megadyne Mega Soft Patient Return Electrode, Product Codes: 0800, 0800S, 0830, 0830S, 0835, 0835S, 0840, 0840S, 0845, 0845S, 0846, 0846S, 0847, 0847S, 0848, 0848S/International Service Centers qualified by Ethicon Endo-Surgery, Inc. (Ethicon) at 4545 Creek Road, Cincinnati, OH 45242*

2. Compliance Assessment (GxP applicability)

Determine the GxP applicability of the system or change using the high-level questions in the table below. For the purpose of this assessment the term “system” refers to the process/equipment/change being evaluated.

No.	Question	Answer	Comment
1	Can the system come in direct contact with the product?	Yes ☒ No ☐	The service line and process contain controlled devices that come in contact with the Mega Soft being serviced.
2	Can the system interact with or provide elements that come into contact with product or product components?	Yes ☒ No ☐	The service line and process interact with controlled devices and parts that come in contact with the Mega Soft being serviced.
3	Is the system used in cleaning, or sterilizing product or materials?	Yes ☐ No ☒	☒ N/A
4	Can the system control environmental conditions critical to the manufacture of a product or preserve product status?	Yes ☐ No ☒	☒ N/A
5	Can the system produce data, which is used to accept or reject product?	Yes ☒ No ☐	The service line and process system produce data which is used to accept or reject product.
6	Is the system a process control system (e.g. PLC) that may affect product quality?	Yes ☐ No ☒	☒ N/A

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No.	Question	Answer	Comment
7	Can the system supply a utility or function to a GMP system?	Yes ☒ No ☐	Production and process controls. The service process that will be validated will supply records/documentation to the Service Database.
8	Can the system affect the performance of a GMP system?	Yes ☒ No ☐	Production and process controls.
9	Can the system monitor or control a critical or key operational or performance parameter?	Yes ☒ No ☐	The service line and process have outputs related to performance to parameters.
10	Will failure or alarm of the system have a direct effect on product quality where the failure or alarm is not detected in the same system or a separate system?	Yes ☒ No ☐	The failure will have direct effect on the product quality because the service and repair process will affect product quality.
11	Is the information from this system recorded in the DHR in order to release product or used to make quality decisions in other GMP documentation (e.g. maintenance, calibration, cleaning, complaints etc.)?	Yes ☒ No ☐	The service line and process produce records for Device History Records (Service Records) (e.g., maintence, calibration, cleaning, complaints).
12	Can the system control the process elements in such a way as to affect product quality?	Yes ☒ No ☐	The service line and process control the process steps in such a way to effect product quality.
13	Is the system involved in packaging or labelling?	Yes ☐ No ☒	Packaging and labelling is not considered part of the service and repair process.
14	Can the system support calibration, testing?	Yes ☒ No ☐	Within the service and repair process, there is a calibration step.
15	Can the system use electronic signatures for GxP relevant data approvals or can it store electronic records that are related to GMP records, such as: Batch records, maintenance records, SOP's, calibration, cleaning, sterilization, device history file, device master file, complaint records, product specifications, internal audit records, laboratory records?	Yes ☐ No ☒	All devices used in the process return to "blank" after data is collected and printed or viewed.
16	Can the system track the process steps relating to the manufacture of a GMP product?	Yes ☒ No ☐	The service line and process produce forms that document the process steps and results of service and repair.

If any questions in the table above are answered with a "**Yes**" response, then the system or change **has GxP applicability**, therefore, **Validation or Verification** is required.

If all questions in the table above are answered with a "**No**" response, then the system or change **has no GxP applicability** and the system or change can be implemented directly without **Validation or Verification**.

3. Computer Software Validation of Equipment (CSV-E) assessment

CSV activities will be performed per instructions in PR-0000089 Franchise Procedure for Validation. An equipment software validation is not required due to the fact that the equipment has off the shelf software installed by the manufacturer.

4. Process Validation / Process Verification path

N/A all boxes if the change has no impact on the process and therefore process validation/verification is not required.

Process Validation	**Yes** ☐ / **No** ☐ / **N/A** ☒ Provide rationale below: Both process verification and validation required.
Process Verification	**Yes** ☐ / **No** ☐ / **N/A** ☒ Provide rationale below: Both process verification and validation required. Reason for Process Verification: ☐ There is a special customer need that requires verification (e.g. Custom Medical Devices) ☐ The annual production volume does not support a statistically sound sampling strategy for validation. ☐ Other: Please explain. _____ _____

Both Process Verification/ Process Validation activities	**Yes** ☒ **/ No** ☐ **/ N/A** ☐ Provide rationale and define which asset will be verified and which one validated: The evaluation steps within the process of service for the Mega Soft Patient Return Electrode will be validated by objective evidence that the process consistently produces a result meeting its predetermined specifications. The service and repair bench setup will be verified by examination and provision of objective evidence that specified requirements that have been fulfilled. Final QA verification will be used as evidence of the service and repair validation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

5. Required Validation Deliverables

No.	Question	Answer	Outcome
1	Is the equipment measuring / controlling a critical process parameter?	Yes ☒ No ☐	If Yes, the equipment requires an IQ, skip to question 3. If No, go to question 2.
2	Is the equipment requiring a permanent or semi-permanent installation and connection to utilities (e.g. it is not a plug&play equipment)?	Yes ☐ No ☐ N/A ☐	If Yes, the equipment requires an IQ, go to question 3. If No, the equipment may not require an IQ. Justify here the risk based rationale for no IQ: _____ _____ _____
3	Is the equipment portable?	Yes ☐ No ☒	If Yes, go to Question 4. Test for portability in the IQ. If No, skip to Question 5.
4	Has the equipment portability been previously qualified?	Yes ☐ No ☐ N/A ☐	If Yes, record reference _____ If No, Include test for portability in IQ
5	Has the IQ been previously completed for the Equipment?	Yes ☐ No ☒	If Yes, move to next question to determine requirement. If No, IQ is required.
6	Is there a change to the location / utilities?	Yes ☐ No ☒	If Yes, IQ is required. OQ, PQ and/or Verification Study may be required.
7	Can the change potentially affect Safety/Process controls on the Equipment?	Yes ☒ No ☐	If Yes, IQ is required.
8	Is the change involving a duplicate equipment?	Yes ☐ No ☒	If Yes, IQ, then either OQ or PQ are required
9	Can the change affect the range of parameters for the Process?	Yes ☐ No ☒	If Yes, OQ (or Process Verification Study if needed) is required.
10	Can the change affect the worst-case product/conditions for the Process?	Yes ☐ No ☒	If Yes, OQ (or Process Verification Study) is required.

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No.	Question	Answer	Outcome
11	Can the change affect the fixed nominal parameters within the parameters range validated in OQ? Or can the change impact CTQ's and the change is within existing validated range (verified by data)?	Yes ☐ No ☒	If Yes, PQ/Process Confirmation Run (or Proces Verification Study) is required.
12	Is the change a new product/process introduction?	Yes ☒ No ☐	If Yes, OQ & PQ (or Process Verification Study) is required.

Note: if additional details are needed, document them in the validation plan or protocol.

6. Validation Plan & Validation Summary Report Determination

No	Question	Answer	Comments
1	Is this a project involving more than one system, equipment, and/or processes?	Yes ☒ No ☐	Introducing a process that will be made up of multiple process steps involving multiple pieces of equipment
2	Is this a Validation/ Verification of new product introductions?	Yes ☒ No ☐	This is a service validation/verification for a new product introduction (new to the service centers).
3	Does this project include validations/ verifications for process transfers between sites?	Yes ☐ No ☒	This is not a process transfer. This is considered a new process introduced at International Service Centers.

If any questions in the table above are answered with a "**Yes**" response, then **a Validation Plan and Validation Summary Report are required**.

If all questions in the table above are answered with a "**No**" response, then **a Validation Plan and Validation Summary Report are not required** but may be created at the discretion of the Project Team. In this case, indicate below if a Validation Plan/Validation Summary Report will be created:

Yes ☒ No ☐

7. Comments

An OQ is not required since the associated process equipment have single point operational parameters and not operational ranges.

An Equipment software validation is not required due to the fact that the equipment that will be used in this service process has off the shelf software installed by the manufacture.

Validation Plans, Installation Qualifications, Performance Qualifications, and Validations Summaries will be created for each International Service Center to be qualified. Validations will follow the intent and templates of PR-0000089, but will be executed and documented using the document control system of the each international center.

☐ **None**

8. Originator

Name/Title	Signature	Date
Jason Stivers	eSig in EPICENTER	eSig in EPICENTER

9. Approvals

Name/Title	Signature	Date
Service Manager Shannon Gillespie, Service Manager	eSig in EPICENTER	eSig in EPICENTER
Engineering Ibrahim Bitar, Service Engineer	eSig in EPICENTER	eSig in EPICENTER
Quality Robert Peters, Customer Quality Team Lead	eSig in EPICENTER	eSig in EPICENTER