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COMPLETION REPORT APPROVAL PAGE

COMPLETION REPORT #	PRC097119	REVISION:	A	DATE:	08/14/2020
PROTOCOL #	PRC097117	MVP, ECP, DP or SPCR#			DC003495

TITLE:	Completion Report of E20291 MaxID: ES2910, PTFE Refrigeration Station Software Validation

STATUS	☒ SALEABLE	☐ NON-SALEABLE	☐ N/A

COMPLETION REPORT INFORMATION			
ORIGINATOR:	Osvaldo Mendez	PHONE NUMBER:	3102
ORIGINATOR TITLE:	Engineer II	SITE:	Independencia Plant

PRIORITY STATUS (Specify Document Due Date):	N/A

Refer to Protocol Document for Type and Approval Governance Information

APPROVAL LIST:

Function	Name	User I.D.	Signature/Date
ORIGINATOR	Osvaldo Mendez	OMendezC	eSing in EPICENTER
MEST Equipment Eng.	Javier Diaz	JDiaz24	eSing in EPICENTER
Plant Quality Eng.	Victor Cantu	vcantusi	eSing in EPICENTER
BU Manufacturing Eng.	Irvin Rivera	Iriver36	eSing in EPICENTER
Lifecycle Quality Engineer	Ihsan Samara	isamara	eSing in EPICENTER

Additional Completion Approvals (N/A If Not Applicable)

Function	Name	User I.D.	Signature/Date
Test Conducted By	Navidad Catemaxca	NCatemax	eSig in EPICENTER
Data Authentication	Osvaldo Mendez	OMendezC	eSig in EPICENTER
Product Destroyed By	N/a	n/a	n/a

DISTRIBUTION LIST: (create as necessary)

Revision	Change Description
A	Original Issue

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1.0 SUMMARY

1.1 This Completion Report intends to document the results obtained from the execution of the Software Validation Protocol PRC097117 Rev A.

1.2 The software SRC003419 that contains LabView program for PTFE Refrigeration Station E20291 Maximo ID ES2910 was installed properly and met requirements established in Appendix 1 of protocol PRC097117 Rev A.

2.0 CRITERIA FOR SUCCESS

2.1 Required: The “Actual Results” shall be the same as the “Expected Results” for each test case.

2.1.1 Results All “Actual Results” match the “Expected Results” for each test case as documented in Attachment II of this Completion Report.

2.2 Required: For each discrepancy in each test case, a root cause analysis shall be performed, the solution(s) implemented, and test case repeated to verify that the solution(s) are correct and effective. Document the corrective action and results in the Completion Report.

2.2.1 Results: There was no discrepancy resulted from the execution of protocol PRC097117 Rev A. The “Expected Results” for each of the test case matched with corresponding “Actual Results”. No corrective action required.

3.0 TEST SUMMARY

3.1 Software Validation Test Cases mentioned in PRC097117 Rev A were executed for equipment PTFE Refrigeration Station E20291 Maximo ID E20291, located in Megadyne Packaging Line 173.

3.2 **Testing Location:

☐ Cincinnati Campus (all buildings): Ethicon Endo-Surgery, Inc. 4545 Creek Road, Cincinnati, OH, 45242
☐ Albuquerque: Ethicon Endo-Surgery, 3801 University Blvd, S.E., Albuquerque, NM, 87106
☐ Torres: Ethicon Endo-Surgery, S.A. de C.V., Avenida De Las Torres No 7125, Colonia Savarcar 118, Ciudad Juarez, Chihuahua, 32580, Mexico
☒ Independencia: Ethicon Endo-Surgery, S.A. de C.V. Planta II, Calle Durango No. 2751, Colonia Lote Bravo, Ciudad Juarez, Chihuahua, 32575, Mexico
☐ Other (please specify): n/a

4.0 OVERVIEW OF FACTS/RESULTS

4.1 The Software SRC003419 Rev A, has demonstrated to correctly operate the equipment and comply with the Test Cases requirements. All test cases were performed and completed successfully.

4.2 All “Actuals Results” matched “Expected Results” in each Test Case therefore Criteria for Success was met as stated in PRC097117 Rev A.

4.3 “Actual Results” of all Test Cases are documented in Attachment II.

4.4 Training was given to the executioner of protocol. Training record is included in this Completion Report as Attachment I.

5.0 RECOMMENDATIONS

5.1 It is recommended that, once this Completion Report is released, upload SRC003419 Rev A, that operates the PTFE Refrigeration Station E20291 Maximo ID ES2910 into Epicenter for review and approval under ECN031250. Once approved, release for deployment into the production environment.

6.0 APPENDICES

6.1 Attachment I - Training Record

6.2 Attachment II - Equipment Software Test Cases Results

6.3 Attachment III - Required Printout for Test Cases.

7.0 Supporting Files

7.1 Equipment Source code SRC003419.

8.0 Maximo Work Order Reference:

8.1 Maximo WOs 10001969042 NUPROD were generated to document the software installation and test of SRC003419 Rev A. Once this source code is approved, issued for implementation and successfully installed, this WO will be closed.

9.0 SUMMARY OF COMPLETION ACTIVITIES

9.1 This software will be recorded and retained in Epicenter system under the following ECN number and Source Code will be released upon successful completion of DC003495.

Software #	Rev	Equipment #	Equipment Name	Production Line	Controller Type	Program Type	ECN #	Maximo ID
SRC003419	A	E20291	PTFE Refrigeration Station.	173	PC	Software LabView	ECN031250	ES2910

Table 2 ECN Software Implementation