



DOCUMENT CONTROL DEPARTMENT
Document Transfer Approval Form

☒ ECO #: CA23797
☐ Eng. Study #: _____
☐ Validation #: _____
☐ Qualification #: _____

E-mail subject: MVP for Your approval_
Attention to: Jake Warren JWarren@synergeticsusa.com

If urgent please check ☒

Purpose of Transfer:

Review and approval

Documents Attached: (If applicable)

Document	Revision	☐	Document	Revision	☐
MVP V3599	A	☐			☐

Reference Documents: (If applicable)

Document	Revision	☐	Document	Revision	☐

Cesar Gomez 20/05/16
Lake Region Medical Juárez, Requestor
(Name, Signature, Date)

O. Durán
Ogadaí Durán May-20-2016
Lake Region Medical Juárez, Doc. Control
Approval
(Name, Signature, Date)

Change Approval No.:	CA23797
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Section I / Sección I

Type of change / Tipo de cambio		Type of document / Tipo de documento	
☐ New document / Nuevo documento ☒ Revision / Revisión ☐ Temporary Deviation / Desviación Temporal Expiration Date / Fecha de expiración		MVP Master Validation Plan Training Required / Entrenamiento requerido ☒ Yes ☐ No	
Labeling Verification by: / Etiquetas Verificadas por: Document(s) affected: / Documento(s) afectados: MVP V3599 Rev.New		Labeling / Etiquetado Change affects labeling? / Afecta el cambio las etiquetas? ☐ Yes ☐ No	
		Date: / Fecha: N/A	

Oracle Requirements / Requerimientos de Oracle			
Does the change affects Oracle? / Afecta el cambio a Oracle? ☐ Yes ☒ No	Update Item Master / BOM / Actualizar Item Master / BOM ☐ Yes ☒ No		
Does change affect cost or price? / El cambio afecta precio o costo? ☐ Yes ☒ No	Master Lists Update required / Requiere actualización de lista maestra ☒ Yes ☐ No		

If change involves update in components or BOMs specify the following / Si el cambio involucra cambios en componentes o BOMs especifique lo siguiente:	
Current Part Number and Rev: / Número de parte y revisión anterior: N/A	Type of Implementation / Tipo de implementación ☐ A Stop Production and implement immediately once documentation / material is available / Parar producción e implementar cambio inmediatamente. ☐ B Continue Production and change as soon as material or documentation is ready / Implementar cambio en cuanto material o documentación este lista ☐ C Incorporate change when all material has been depleted. No obsolescence / Incorporar cambio cuando todo el material se haya terminado. No obsoletizar.
New Part Number and Rev: / Número de parte y revisión nueva: C. Gomez 14/05/16	

Description of the change: (Marked up documents may be attached) / Descripción del cambio (documentos marcados pueden ser anexados)

Release of MVP V3599 Rev.A with the following changes:
 1.- Change revision from Rev. New to Rev. A
 2.- Change of the Approvals matrix(table 3), in order to include the customer approval for PQ and MVP.
 See redline only as reference.

Reason of the change: (Attach supporting data) / Razón del cambio (Anexe datos de respaldo)

The customer does not included on the approval matrix, it is necessary that customer approve the MVP's and PQ's before start any validation activity.

Justification: (Attach Support Data) Explain / Justificación (añadir datos de respaldo) Explicar:

The customer must to approve the MVP and PQ's before start any validation activity, originally the customer was not included.

ORIGINATOR Originador C. Gomez 14/05/16		Requested Date Fecha de Requisición 19-May-16	
☒ Quality Assurance / Date Aseguramiento de calidad / Fecha	☒ Manufacturing / Date Manufactura / Fecha	☒ Engineering / Date Ingeniería / Fecha	☐ Materials / Date Materiales / Fecha
☐ Finance / Date Finanzas / Fecha	☒ Customer / Date Cliente / Fecha	☒ Other / Date Other / Fecha	☒ Other / Date Other / Fecha

CA23797

Date / Fecha:

(For internal purposes only / Para uso interno solamente)

Signature / Firma:

Ingeniero de calidad notificado:

[illegible]

Finance / Date
Finanzas / Fecha

Product name: Synergetics Cord Tubing Sets
Protocol No.:
V3599
Process name: Validation of new molding process on Arburg 55 Ton molding machine, New Stripping process on Schleuniger UniStrip 2600, New crimping process on Kenco crimping machine using new Heyco crimping tool Synergetics products.
Revision:
A~~New~~
Form No.: MSC-04.35, Rev 5
Effective date: 7 August 2015
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TABLE OF CONTENTS

1.0	General Information.....	2
2.0	Approvals	3
3.0	Purpose / Objective	3
4.0	Scope.....	3
5.0	Background.....	3
6.0	Reference Documents.....	5
7.0	Responsibilities	6
8.0	General Assumptions and Prerequisites.....	6
9.0	Product Grouping	7
10.0	Sterilization Conditions.....	7
11.0	Validation Strategy	7
12.0	Acceptance Criteria, Statistical Methods, and Sample Size Justification	7
13.0	MVP Status and Re-Validation Requirements	8
14.0	Attachments	8
15.0	Revision History	8

Product name: Synergetics Cord Tubing Sets

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V3599

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Revision:

ANew

Form No.: MSC-04.35, Rev 5

Effective date: 7 August 2015

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CA23797
23556

1.0 GENERAL INFORMATION

1.1 Title: Master Validation Plan for Manufacturing Process Line for Synergetics Rotary Feed Cord Tubing Sets p/n 125742 and Gravity Pump, Cord Tubing Set p/n 125024.

1.2 Refer to Table 1 for general information pertaining to the qualification.

Table 1 — General Information			
Master Validation Plan Number and Rev	V3599 REV. NEW	Process No. and/or name	Synergetics Manufacturing Process
Project Number and/or Name	Synergetics	Prepared by date	March 18 2016
Prepared By	C. Gomez	Equipment Description	Arburg 55Ton Molding Machine, Schleuniger UniStrip 2600 Stripper Machine, Kenco 5K5170 Crimping Machine, Heyco 8033 Crimping Tool.
Equipment ID and Rev.	234764-M, US2600, 20161001, 8033	Location w/in Facility	Clear Room 2, Plant 1
Facility Name	LRM, Juarez	Other	N/A

Table 2 — Product References		
Product Groups	Item Numbers	Customer #
Rotary Feed, Cord Tubing Sets	125742 Rev.006	72061082 Rev. D
Gravity Pump, Cord Tubing Set	125024 Rev.005	72060554 Rev. G

Product name: Synergetics Cord Tubing Sets

Protocol No.: V3599

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 ECO No.: CA23797
23556

2.0 APPROVALS

2.1 Documents will be approved in accordance and requirements of table 3.

Table 3 — Approval Matrix					
Signoff Required	Component Qualification	IQ	OQ	PQ	MVP
Quality Engineering	N/A	X	X	X	X
Engineering	N/A	X	X	X	X
Manufacturing (Operations)	N/A	X	X	X	X
Customer	N/A	N/A	N/A	<u>X</u> N / A	<u>X</u> N / A

3.0 PURPOSE / OBJECTIVE

3.1 The purpose of this master validation plan is to document the guidelines necessary for the validations of new Arburg 55Ton Molding Machine, Schleuniger UniStrip 2600 Stripper Machine, Kenco 5K5170 Crimping Machine and Heyco 8033 Crimping Tool.

4.0 SCOPE

4.1 This Master Validation Plan applies to the Synergetics Rotary Feed Cord Tubing Sets p/n 125742 Rev. 005 and Gravity Pump, Cord Tubing Set p/n 125024 Rev. 006.

5.0 BACKGROUND

5.1 Wire Stripper

5.1.1 Current stripping process is performed using the ARTOS stripping machine, this machine was installed and validated, the machine already exceeded the usable life time making it an obsolete machine and making difficult the availability of spare parts, or any support from machine manufacturer, creating downtime and increasing the amount of scrap during adjustments and repairs.

5.1.2 The Wire stripper Schleuniger UniStrip 2600 machine was acquired to replace current stripper machine to reduce the overall downtime generated by adjustments and repairs.

5.1.3 The new wire stripper machine will be validated under MVP 3599 Rev. New.

5.1.4 PQ for the stripping process is required as part of the product validation.

Product name: Synergetics Cord Tubing Sets

Protocol No.:

V3599

Process name: Validation of new molding process on Arburg 55 Ton molding machine, New Stripping process on Schleuniger UniStrip 2600, New crimping process on Kenco crimping machine using new Heyco crimping tool Synergetics products.

Revision:

ANew

Form No.: MSC-04.35, Rev 5

Effective date: 7 August 2015

Status: Released

ECO No.:

 CA23797
 23556

5.2 Molding Machine

- 5.2.1 The Synergetics manufacturing line requires an over molding process in the cable set. Once over molding process has been concluded, manufacturing operator frequently find defects such as sinking and flash. The investigation lead to conclude that unacceptable visual conditions are generated during over molding process since Gluco molding machine does not have the stability to keep the process free of visual conditions defects since machine already exceeded the usable lifetime.
- 5.2.2 Therefore, in order to address quality molding related issues as well as manufacturing process improvements, New molding machine Arburg 55 Ton will be validated with new Molding process parameters this validation will confirm that new parameter does not have an effect adverse on the product and meet current customer requirements.
- 5.2.3 The new Molding machine will be validated under MVP 3599 Rev. New.
- 5.2.4 OQ and PQ for the Molding process is required as part of the product validation

5.3 Crimping Machine

- 5.3.1 Currently the crimping process for Heyco terminal it is performed by the Heyco crimping press with the crimping tool AC11-416. To perform the crimping of the terminal a periodic lubrication it is necessary to prevent the terminal get stuck at the top of the die (Anvil) to prevent this condition it was requested to the supplier a new design of crimping tool which not use lubricant.
- 5.3.2 A new crimping machine (Kenco 5K5170) and new crimping tool (Heyco 8033) was acquired to eliminate the use of lubricant.
- 5.3.3 The new Crimping press and crimping tool will be validated under MVP 3599 Rev. New.
- 5.3.4 PQ for the crimping process is required as part of the product validation

Product name: Synergetics Cord Tubing Sets

Protocol No.:

V3599

Process name: Validation of new molding process on Arburg 55 Ton molding machine, New Stripping process on Schleuniger UniStrip 2600, New crimping process on Kenco crimping machine using new Heyco crimping tool Synergetics products.

Revision:

ANew

Form No.: MSC-04.35, Rev 5

Effective date: 7 August 2015

Status: Released

ECO No.:

 CA23797
 23556

6.0 REFERENCE DOCUMENTS

6.1 Refer to Table 4 for a list of referenced document numbers, which includes descriptions and revision number for each referenced document.

Table 4 — Reference Documents		
Document Identification Number	Rev.	Title
CWS-04-11	17	Process Qualification and Validation Procedure
CWS-04-12	11	Failure Mode Effects Analysis (FMEA) and Risk Analysis Procedure
CWS-04-21	9	Pilot Work Order Procedure
CWS-20-01	4	Statistical Techniques Procedure
039.SOP	Q	Good Document Practice
034.SOP	O	Device Master Record Composition
038.SOP	AK	Verification and Validation
076.SOP	Y	Training
003.SOP	AAG	Document and Data Control
011.SOP	P	Product Identification and Traceability
012.SOP	AX	Handling, Storage, Packaging, Preservation and Delivery
005.SOP	AP	Non-Conforming Product Control
125742-L	AC	Layout for the product of Synergetics 125742
125024-L	AY	Layout for the product of Synergetics 125024
125742	006	Product specification
125024	005	Product specification
Control Plan	New	Synergetics Control Plan p/n 125024
Control Plan	B	Synergetics Control Plan p/n 125742
PFMEA	A	Synergetics PFMEA p/n 125742
Q3339	N/A	Wire stripper Schleuniger UniStrip 2600
Q3685	N/A	Arburg All-rounder 375 V 500 -100 Molding machine

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Revision:

ANew

Form No.: MSC-04.35, Rev 5

Effective date: 7 August 2015

Status: Released

ECO No.:

 CA23797
 23556

Table 4 — Reference Documents

Document Identification Number	Rev.	Title
Q3687	N/A	Arburg All-rounder 375 V 500 -100 Molding machine
V3650	New	Validation of new molding process for Rotary Feed, Cord Tubing Set 125742 Arburg Molding Machine.
V3651	New	Validation of new Molding process and new Stripping process for Rotary Feed, Cord Tubing Set 125742on Gluco mold machine.

7.0 RESPONSIBILITIES

- 7.1 Manufacturing Engineering and Quality Engineering are responsible for creating necessary build paperwork, Maintenance Work Instructions and development forms, training of operators, overseeing builds as required to make product needed for the execution of this plan. Manufacturing Engineering will create this protocol and any subsequent updates and reports that are required based upon the results of the corresponding qualifications.
- 7.2 Quality Assurance is responsible for overseeing validation builds, performing and recording all quality testing. Develop and implement applicable quality system requirements, train quality inspectors on all testing related activities, validate all methods, label verification, review and approve MVP and required protocols, reports and all quality system related documentations.
- 7.3 Operations is responsible for manufacturing and building the production of the validation builds, review and approve protocols.
- 7.4 Facilities Engineering is responsible for ensure that all power requirements, water utility, drainage utility, waste disposal, ventilation, chemicals storage, are accounted for in the IQ's. Ensure that manufacturing Equipment is maintained and qualified.

8.0 GENERAL ASSUMPTIONS AND PREREQUISITES

- 8.1 The MVP must be approved prior to execution of any validation activities under a protocol. IQ can proceed prior to the release of the MVP.
- 8.2 Manufacturing and test equipment shall be within its established calibration cycle prior to production or testing of devices.
- 8.3 All validation studies will be performed to approved protocols in accordance with the Process and Validation Procedure (CWS-04-11). Protocols will be approved prior to execution of the validation studies
- 8.4 At the conclusion of the execution of each protocol, a final report will be written documenting the results of the study as well as any deviations to the protocol. The approval requirements for the final report are the same as for the protocol

Product name: Synergetics Cord Tubing Sets

Protocol No.:

V3599

Process name: Validation of new molding process on Arburg 55 Ton molding machine, New Stripping process on Schleuniger UniStrip 2600, New crimping process on Kenco crimping machine using new Heyco crimping tool Synergetics products.

Revision:

A~~New~~

Form No.: MSC-04.35, Rev 5

Effective date: 7 August 2015

Status: Released

ECO No.:

CA23797
23556

- 8.5 Where appropriate, test methods will represent those used by the customer unless otherwise justified. Test methods will be qualified, validated or have a valid gage R&R completed, prior to using the test method to establish conformance to specifications.

9.0 PRODUCT GROUPING

- 9.1 Due to Over Molding, Wire Stripping and Crimping process for the manufacturing of Synergetics, products are the same for both part numbers 125742 and 125024, but product code 125024 requires a few extra steps and equipment it has been selected to represent both Synergetics codes.

10.0 STERILIZATION CONDITIONS

- 10.1 This is a non-sterile item; therefore, sterilization is not required prior to testing

11.0 VALIDATION STRATEGY

11.1 Process Validation Strategy

- 11.1.1 IQ/OQ/PQ, Will be performed as described in Table 6.
- 11.1.2 All validation requirements will be established based upon process or product risk analysis.

11.2 Component (Supplier) Qualification Strategy

- 11.2.1 All components (with suppliers) and validation requirements are listed in Table 8.
- 11.2.2 All suppliers will be qualified in accordance with CWS-06-01
- 11.2.3 No supplier qualification is required as this product components will be receive in the LRM facility certified (CoC) from supplier, the quality incoming inspection department will inspect the incoming certified components per correspondent specification in LRM Jrz.

11.3 Software Validation Strategy

- 11.3.1 There is no manufacturing software required to produce Synergetics products and no software validation is required.
- 11.3.2 For the molding machine software, it is considered that this software falls in the category of "firmware", which means that it can be configured during the set up but cannot be altered by the user

11.4 Test Method Validation Strategy

- 11.4.1 All test methods used and their qualification requirements have be listed in Table 7.

Product name: Synergetics Cord Tubing Sets

Protocol No.: V3599

Process name: Validation of new molding process on Arburg 55 Ton molding machine, New Stripping process on Schleuniger UniStrip 2600, New crimping process on Kenco crimping machine using new Heyco crimping tool Synergetics products.

Revision: ANew

Form No.: MSC-04.35, Rev 5

Effective date: 7 August 2015

Status: Released

ECO No.: CA23797
23556

- 11.4.2 For the molded parts a First Article Inspection FAI it is applicable in order to ensure the compliance with the customer specifications

12.0 ACCEPTANCE CRITERIA, STATISTICAL METHODS, AND SAMPLE SIZE JUSTIFICATION

- 12.1 Sample size requirements and acceptance criteria for each process output will be defined in the OQ and PQ protocols.
- 12.2 The data collected during the execution of the IQ and OQ and PQ protocols will be analyzed using valid statistical techniques. If variable data is used the mean and standard deviation for each data set will be calculated and assessed for normality.
- 12.3 For the OQ and PQ protocols, statistically significant sample, sizes will be selected based on the product and/or business risks and defined in the protocol.

13.0 MVP STATUS AND RE-VALIDATION REQUIREMENTS

- 13.1 The MVP will be continuously updated as validations are executed and as new equipment and processes are implemented.
- 13.2 Re-qualification or re-validation must be considered in the following cases:
- 13.2.1 Process monitoring indicates a drift in the process, which if continued, will result in an out of control situation
 - 13.2.2 Changes to equipment, software or process parameters
 - 13.2.3 Changes to device design or material specifications
 - 13.2.4 Resumption of production after a shutdown of a significant length of time
 - 13.2.5 Manufacturing site change
 - 13.2.6 Supplier or supplier process change
- 13.3 The extent of the re-qualification/re-validation will depend upon the nature of the changes and how they impact the previously validated process. It may not be necessary to completely revalidate a process merely because a given circumstance has changed.

14.0 ATTACHMENTS

- 14.1 N/A

15.0 REVISION HISTORY

Revision	Approval Date	Effective Date	ECO Number	Reason for Revision
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Product name: Synergetics Cord Tubing Sets

Protocol No.:

V3599

 Process name: **Validation of new molding process on Arburg 55 Ton molding machine, New Stripping process on Schleuniger UniStrip 2600, New crimping process on Kenco crimping machine using new Heyco crimping tool Synergetics products.**

Revision:

ANew

Form No.: MSC-04.35, Rev 5

Effective date: 7 August 2015

Status: Released

ECO No.:

 CA23797
 23556

New	<u>May-12-16</u>	<u>May-13-16</u>	CA23556	New Release
<u>A</u>			<u>CA</u>	<u>Table 3 changes to include customer aprovals.</u>

Product name: Synergetics Cord Tubing Sets Protocol No.: V3599

Process name: Validation of new molding process on Arburg 55 Ton molding machine, New Stripping process on Schleuniger UniStrip 2600, New crimping process on Kenco crimping machine using new Heyco crimping tool Synergetics products.

 Revision: A^{New}

 Form No.: MSC-04.35, Rev 5 Effective date: 7 August 2015 Status: Released ECO No.: CA23797
23556

Table 6 — Process Validation Plan

Process (Work Instruction)	Process Outputs	Report Required (Yes or No For Required. Once completed, list Report Number)			Software Validation	Comments
		IQ	OQ	PQ		
3099.EWI	Splint wire, proximal cut length	No	No	No	Software validation is not required since any machine or equipment is not required to perform assembly process.	Note 1: Installation Qualification (IQ) is not required due to the process is manual assembly no machine or equipment it is required, Note 2 An Operational Qualification (OQ) is not required due to the process for the assembly not use any machine or equipment that has parameters to be challenged. Note 3: Performance Qualification (PQ) must be performed under validation protocols: V3651 V3660
3100.EWI	Wire coil length	No	No	No		
3108.EWI	Spike with cap, Assembly strength	No	No	No		
3109.EWI	Assembly strength	No	No	No		
3232.EWI	Assembly strength	No	No	No		
3235.EWI	Assembly strength	No	No	No		
3580.EWI	Packaging Configuration	No	No	No		
3709.EWI	Good/Bad Parts	No	No	No		
7005.EWI	Packaging Configuration	No	No	No		
8337.EWI	Assembly strength	No	No	No		
8430.EWI	Good/Bad Parts	No	No	No		

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Governing document CWS-04-11

Template Form MSC-05.18 Rev3

Product name: Synergetics Cord Tubing Sets	Protocol No.: V3599
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Process name: Validation of new molding process on Arburg 55 Ton molding machine, New Stripping process on Schleuniger UniStrip 2600, New crimping process on Kenco crimping machine using new Heyco crimping tool Synergetics products.

Revision: ANew

Form No.: MSC-04.35, Rev 5	Effective date: 7 August 2015	Status: Released
		ECO No.: CA23797 23556

8431.EWI	Good/Bad Parts	No	No	No	These machines works fully electrical-mechanical function does not use software.	V3617
3234.EWI	Assembly strength	Q2330	No	No		
3103.EWI	Crimp strength	Q2327	No	No		
3102.EWI	Crimp strength	Q3706	No	V3660		
3231.EWI	Good/Bad Parts	Q2329	No	No	For these machines software, it is considered "firmware", which means that it can be configured during the set up but cannot be altered by the user	These machines no require validation due to process is fully verifiable.
3477.EWI	Good/Bad Parts	Q2331	No	No		
3218.EWI	Good/Bad Parts	Q2332	No	No		
3106.EWI	Good/Bad Parts	Q2332	No	No		
3101.EWI	Strip cut length, wire integrity	Q3340	No	V3617	Operation Qualification (OQ) is not required since the setup of the machine is programmable according the specifications (cut length, wire diameter, insulating diameter).	Operation Qualification (OQ) is not required since the setup of the machine is programmable according the specifications (cut length, wire diameter, insulating diameter).
7003.EWI	Molded parts	Q3687	V3650	V3651		
8301.EWI	Luer and spike with caps	No	No	No		
			V3035			

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Governing document CWS-04-11

Template Form MSC-05.18 Rev3

Title: MASTER VALIDATION PLAN		Page: 12 of 17
Product name: Synergetics Cord Tubing Sets	Protocol No.:	V3599
Process name: Validation of new molding process on Arbarg 55 Ton molding machine, New Stripping process on Schleuniger UniStrip 2600, New crimping process on Kenco crimping machine using new Heyco crimping tool Synergetics products.		Revision: <u>A</u> New
Form No.: MSC-04-35, Rev 5	Effective date: 7 August 2015	Status: Released
		ECO No.: CA23797 23556

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 Governing document CWS-04-11

Title: MASTER VALIDATION PLAN		Page: 13 of 17	
Product name: Synergetics Cord Tubing Sets	Protocol No.: V3599		
Process name: Validation of new molding process on Arburg 55 Ton molding machine, New Stripping process on Schleuniger UniStrip 2600, New crimping process on Kenco crimping machine using new Heyco crimping tool Synergetics products.		Revision: <u>A</u> New	
Form No.: MSC-04.35, Rev 5	Effective date: 7 August 2015	Status: Released	ECO No.: CA23797 23556

Table 7— Test Method Validation Plan

Test Description	Test Method Number	IQ (Yes or No For Required. Once completed, list Report Number)			Test Method Validation (Yes or No For Required. Once completed, list Report Number)	Comments/Rationale
		IQ Ref#	Software Ref #	Equip #		
Solvent pull test	001.QWI	Q3146	N/A – No Software	LTCM-100	ES1291	N/A
Pump tube test	003.QWI	Q3146	N/A – No Software	LTCM-100	ES1291	N/A
MDT Leak Test	035.QWI	Q1876	N/A – No Software	MDT-1453	ES1196	100% process inspection.
MDT Leak Test	035.QWI	Q1876	N/A – No Software	MDT-1453	ES1196	100% process inspection.
Pull test	669.QWI	Q3146	N/A – No Software	LTCM-100	V3417	N/A
Hi-pot Test	251.QWI	Q2332	N/A – No Software	Quad Tech sentry 20 plus	ES1294	100% process inspection.

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Form No.: MSC-04.35, Rev 5	Effective date: 7 August 2015
Status: Released	ECO No.: CA23797 23556
	Revision: ANew

Table 8— Component-Supplier table

Component Description (Number)	Supplier Name (Approval Date)	Place X for Required, N/A for not required and report # for completed validations. Justify any N/A entries					Comments (Only required if NA or NR in validation requirements)
		First Article Inspection	Verify or Validate	IQ	OQ	PQ	
125027 Pump Tube (id 0.120", od 0.1")	Saint-Gobain Performance Plastics	N/A	N/A	N/A	N/A	N/A	N/A
125035 Box Sealing Tape for VF	R.S. Hughes Co., Inc.	N/A	N/A	N/A	N/A	N/A	N/A
125045 Reinforced Mex. Pallet	FERNO	N/A	N/A	N/A	N/A	N/A	N/A
125046 Corner Board	XPEDX	N/A	N/A	N/A	N/A	N/A	N/A
125047 1/2 x 9000' Strap	XPEDX	N/A	N/A	N/A	N/A	N/A	N/A
125065 Bushing for VF	Kelcourt Plastics, Inc.	N/A	N/A	N/A	N/A	N/A	N/A
125067 Adapter	Ark-Plas Products Inc.	N/A	N/A	N/A	N/A	N/A	N/A

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---	----------------------------

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Revision: ANew

Form No.: MSC-04.35, Rev 5	Effective date: 7 August 2015	Status: Released	ECO No.: CA23797 23556
-----------------------------------	--------------------------------------	-------------------------	----------------------------------

125068 Vented MLS Cover	Merrit Medical Systems, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
125069 Silicone tube	Saint-Gobain Performance Plastics	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
125085blue Polybag For Rotary	Polyrol Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
125231 Synergetics Carton	International Paper	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
125288 Shield for Male Luer Slip	Comef SPA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
125300 Halkey Clamp	Industrie Borla Spa	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
125608 Thermal Transfer Paper	General Labels	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
125682 Paratube Extrusion (wire 24 AWG)	Pexco	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
125688 PVC (ID 0.118", OD 0.165")	Kelcourt Plastics, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
125709 Cyclohexanone	United Selective Products LLC	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
125710 Isopropanol	United Selective Products LLC	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
125713 Colorite	Colorite	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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Title: MASTER VALIDATION PLAN

Page: 16 of 17

Product name:	Synergetics Cord Tubing Sets	Protocol No.:	V3599
Process name: Validation of new molding process on Arburg 55 Ton molding machine, New Stripping process on Schleuniger UniStrip 2600, New crimping process on Kenco crimping machine using new Heyco crimping tool Synergetics products.		Revision:	A New
Form No.:	MSC-04.35, Rev 5	Effective date:	7 August 2015
		Status:	Released
		ECO No.:	CA23797 23556

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Revision: A ^{New}	
Form No.: MSC-04.35, Rev 5	Effective date: 7 August 2015
Status: Released	ECO No.: CA23797 23556

127091 Pump Adapter	Venus	N/A	N/A	N/A	N/A	V1704 V3472 V3402	N/A	N/A
218364 Vented Spike Shield	Venus	N/A	N/A	N/A	N/A	V2725 V3476 V3516	N/A	N/A