Document Title:	User Requirement Specification
Document No.:	AEU00580

Doc. Issue No.	Date	Author	Revisions Justification
			Change No.
1	9th October 2015	Scott Franklin	0

Document approval for Use

The signatures below signify acceptance of the specification for use.

Signature ..... **Date** 10th NOV 2015
Print Name Scott Franklin
Title (Author) Site Operations Manager

Signature ..... **Date** 10 Nov 2015
Print Name Gary Crawley
Title Head of Quality

Signature ..... **Date** 10 NOV 2015
Print Name Graham Perkins
Title Medical Account Manager

Signature ..... **Date** 10/11/2015
Print Name JAMES ROCHE
Title Customer approval

Signature ..... **Date** 10-Nov-2015
Print Name Brodde Andreas
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Notes to Signatories

Pre-approval

Author

Signature recognises that the report has been prepared accurately and to the correct standard.

Authorisation

Signature recognises that the report has been prepared as a component of the control system validation and authorises the document for use.

Change History

Iss	Section	Change Details
01	N/A	First Issue

1. GENERAL INFORMATION.

1.1. Purpose:

The purpose of this document is to define the customer requirements of spring no: PDR-0000397 v1.0

1.2. Scope:

This document relates to the manufacture verification and supply of the spring no: PDR-0000397 v1.0

1.3. Terms and Definitions:

1.3.1. The customer as referred to in this document relates to Flextronics

1.4. Reference documents

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2. MANUFACTURING REQUIREMENTS.

2.1. Manufacturing Environment:

The components shall be manufactured in an environment approved by Advanex. The environment shall be capable of achieving the quality requirements stated within this specification.

2.2. Raw Material Specification:
The component shall be made from the following material:

STAINLESS STEEL TO BS2056 302 S26 GRADE 2 AND EN10270 PT3 GRADE 1.4310.
Diameter 0.203mm ± 0.01mm

2.2.1. All raw materials shall be sampled and inspected in accordance with the relevant Advanex procedure. All raw materials shall have an appropriate Certificate of Analysis (C of A) from the approved supplier.

2.2.2. Component Manufacturing Equipment and Process.
The component manufacturing cell will be made up of the following validated machines and processes:

HIT8 CNC COILING MACHINE & ASSOCIATED DE-COILER
IN-LINE ELECTRIC FURNACE
MULTI STATION CAROUSEL

2.2.3. The raw material control, product handling and manufacturing processes for the component shall be in accordance with the relevant Advanex procedures.

2.2.4. Handling and storage of the components shall be in accordance with the packaging and labelling requirements as specified within this document.

2.3. Component post process cleaning - equipment and process:

2.3.1. The cleaning processes for the component shall be conducted by Advanex.
2.3.2. The validated machines approved for the cleaning of the component are:

- 7 STAGE PICKLE AND PASSIVATE LINE, INCLUDING CENTRIFUGAL SPIN DRYER.

2.3.3. The cleaning processes for the component shall be in accordance with Advanex procedures.

2.3.4. The components will be packing in accordance with relevant procedures.

2.4. Batch Records:

2.4.1. Advanex shall retain all associated production and quality records for a minimum of 7 years from the date of manufacture of the batch. These records shall provide a documented production history allowing traceability to the tool, machinery and materials used and shall be made available to the customer during an audit or if formally requested.

2.4.2. Advanex shall maintain appropriate batch records that provide batch data which can identify:

Batch code (including traceability to any associated sub-batches)
Quantity
Details of the raw material batch and supplier data associated to the batch code
Date of manufacture
Details of the manufacturing equipment used to manufacture
Quality control inspection, test results and in process control records.
Details of the post process cleaning of the batch.

2.5. Batching Rules:

2.5.1. A component batch shall be defined as:

A manufacturing run from a specific coiling tool type in a specific machine incorporating scheduled / routine stoppages. A minimum batch size shall be no less than 50,000 components. A maximum batch size shall be no more than 250,000 components. No more than two raw material batches per component batch.

2.5.2. Scheduled / routine stoppages (not necessitating a batch change) may occur due to:

Shift pattern
Tool Cleaning
Tool replacement or Minor Maintenance (In Coiling Machine)

Note: Coil changes during a batch run are permitted.

2.6. Manufacturing Deviation:

2.6.1. Should any deviation from validated processes or procedures occur the deviation and remedial actions taken will be recorded, documented and referenced within the manufacturing record. Parts manufactured outside of the validated processes or procedures will NOT be sent to the customer.

2.7. Tool Approval and Tool Repairs:

2.7.1. Routine production tool maintenance, tool repairs, tool replacements or adjustments which do not affect the components specified geometry limits are deemed acceptable and shall not require re-approval or re-qualification. The production records shall be completed, to document when this work is conducted.

2.7.2. Advanex shall complete and document an appropriate inspection report prior to production start up to ensure all dimensions remain within drawing tolerance.

2.7.3. Spring tooling repairs, adjustments or process changes that affect the components specified geometry limits shall require customer approval in accordance with Advanex change control procedures.

2.8. Packaging Materials:

2.8.1. Packaging items (bags, boxes, cartons, etc.) used for packaging of the PDR-0000397 v1.0 spring shall be purchased by Advanex against their internally agreed specification from an Advanex approved supplier.

2.8.2. Incoming items shall be accepted into the business in accordance with the relevant Advanex procedure.

2.9. Risk Management:

2.9.1 Validation

An Initial Risk Assessment will be performed to establish the required level of validation. This will be based on the guidance of GAMP5

2.9.2 Bioburden

There are no bioburden requirements for this component. However, this component is a sub-component of an assembly that has a specific CFU requirement and hence will be manufactured accordingly.

2.9.3 Supply

Risks to supply will be included within the Advanex Business Continuity Management System (Internal distribution only)

2.10. Quality Requirements:

2.10.1. Advanex operate a Quality Management System (QMS) in accordance with ISO 9001:2008. Products supplied against this specification shall comply with the Advanex QMS, the associated procedures and approval processes. Appropriate Good Manufacturing Practices shall be followed by Advanex for products supplied against this document.

2.10.2. Component Dimensions

All component dimensions classified as In Process Control (IPC) or Critical dimensions on the component drawing shall be inspected at intervals within Advanex procedures and assessed for process capability.

All component dimensions NOT classified as In Process Control (IPC) or Critical dimensions on the component drawing shall be inspected at intervals within Advanex procedures and assessed for conformance to the specification.

2.11. Supplier Batch Release

A batch of components shall be released upon a satisfactory review of the quality acceptance checks / tests and a review of the associated production records by an authorised representative of Advanex QA department and a certificate of conformity issued.

2.12. Supplier Retained Samples

Advanex shall retain an appropriate number of samples from each batch in accordance with the relevant Advanex procedures. The samples shall be packaged, clearly labelled and retained for a minimum period of 7 years. The samples shall be stored inside a warehousing area which is clean, dry and appropriate for the suitable storage of samples. The packaged samples shall

be stored at ambient temperatures and humidities as considered standard practice.

2.13. Packaging and Labelling for Transportation

The component packaging processes shall be in accordance with table1 below and relevant Advanex procedures.

2.14. Component Expiry Date Information and Labelling

Component expiry date information is not applicable to the component.

2.15. Pallets

Delivery of the components shall be palletised. A pallet can contain multiple batches of components

Pallets must be 4-way entry, size 1200 x 1000mm, shall be in good condition, clean and suitable for mechanical handling and high rise stacking. The loaded pallet must be enclosed by either shrink or stretch wrapping.

Stage	Details	Packaging Item Details				Sealing Method	Labelling	Quantity of Components per Stage	Description
		Descript	Material	Dims	Ref.				
1	Primary Packaging To contain 1000 off components	Poly bag	ESD grade	TBA	Supplier to suit	Double heat seal	Supplier name, part number, description, quantity, AEU batch number	1000 parts	One primary bag containing 1000 components heat sealed and labelled.
2	Secondary Packaging To contain 10 bags from Stage 1	Poly bag	Cleanroom grade	TBA	Supplier to suit	Double heat seal	Supplier name, part number, description, quantity, AEU batch number	10 x 1000 = 10000 parts	One secondary bag heat sealed, containing ten primary bags as above.
3	Transport carton to contain 1 bag from stage 2	Transport carton	Double wall cardboard	TBA	Supplier to suit	Adhesive Tape	Supplier name, part number, description, quantity, AEU batch number	10 x 1000 = 10000 parts per carton	One transport carton labelled and sealed with adhesive tape, containing one secondary bag as above.
4	Number of cartons to suit pallet	Pallet	Wood	1200mm x 1000mm	Supplier to suit	Poly shrink wrapped	Each individual box shall display the labelling details as per stage 3	10000 parts per carton. Maximum 25 cartons (250,000 parts)	Single batch or single spring set (complete batches only)

Table1

2.16. Storage Conditions:

When storage of the component is required outside of the specified manufacturing environment, the components shall be stored within specified packaging in warehousing conditions considered by Advanex as appropriate. The packaged components shall be stored in a warehouse area which is clean and dry. The packaged components are stored at ambient temperatures and humidities as considered standard practice.

NOTE: One bag in the last box of production will be classified as 'stratisfied samples' and labelled as such.

2.17. Transport

Unless otherwise requested the consignment shall be delivered using Advanex approved transport.