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Your signature indicates that this document has been prepared in accordance with company standards or guidelines and adequately reflects the tasks and deliverables necessary.

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Your signature indicates that, you have reviewed this document and that it accurately and completely reflects the tasks and deliverables necessary.

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Your signature indicates that this document complies with company standards or guidelines; and that the documentation and information contained herein complies with applicable regulatory, corporate, divisional/departmental requirements, and current Good Manufacturing Practices.

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1.0 PURPOSE

1.1. The purpose of the document is to define the SOP (Standard Operating Procedures) to be followed by ADVANEX EUROPE Ltd, in order to ensure that the wire forms are manufactured on the MDI (Measured Dose Inhalers) section are done so in a controlled and consistent manner.

2.0 SCOPE

2.1. For the purpose of this SOP manufacturing only includes the forming and in-line heat treatment operations.

2.2. Secondary operations to forming and in-line heat treatment are covered by other SOP's.

2.3. All equipment and processes on the MDI (Measured Dose Inhalers) section have been formally qualified and validated. All personnel working on the MDI section are responsible for ensuring that no changes are made to the process without full change control as defined in SOP/PH001 (Document Number AEU00226).

3.0 TERMS, DEFINITIONS & ABBREVIATIONS

3.1. Cpk. - Capability index.

3.2. QA - Quality Assurance.

4.0 HEALTH, SAFETY & ENVIRONMENTAL

4.1. GMP (Good Manufacturing Practice) guidelines apply (Document Number AEU00389).

4.2. Within the factory area safety footwear is mandatory.

4.3. Within the factory area safety glasses must be worn at all times.

5.0 ASSOCIATED DOCUMENTS

5.1. Machine Log (Document Number AEU00258): Used to any unplanned activity on a machine.

5.2. MDI Daily Machine Maintenance Record (Document Number AEU00394): Used to record completion of planned preventive maintenance activity on a machine.

5.3. MDI Coil Change (Document Number AEU00436).

5.4. Label Preparation (Document Number AEU00437).

5.5. Measurement Procedure for Slipping Clutch (Document Number AEU00433).

5.6. Measurement Procedure for Drum Axle (Document Number AEU00434).

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5.7. Measurement Procedure for Drive Wheel Support Spring (Document Number AEU00435).
5.8. Production Record Sheet: For recording the quantity of parts produced and wire information.
5.9. Correct Usage of Production Bins (Document Number AEU00397).
5.10. Control of Documents (Document Number AEU00002).
5.11. MDI Particulate Separation (Document Number AEU00053).
5.12. MDI Electrical Failure Furnace (Document Number AEU00227).
5.13. MDI Ultrasonic Washing & Packing (Document Number AEU00054).
5.14. MDI Weigh Count (Document Number AEU00056).
5.15. Works Order Instructions: Allowing full traceability for the batch.

6.0 PROCEDURE

6.1. **Production Records.**

6.1.1. All records relating to this SOP are subject to the requirements of SOP Control of Documents (Document Number AEU00002).
6.1.2. The setter must record any unplanned occurrence to a machine on the Machine Log (Document Number AEU00258). This will include machine adjustment, stoppages, tool breakage, wire feed problems etc.
6.1.3. Planned preventive maintenance schedules are described for each machine in the SOP MDI Daily Machine Maintenance Record (Document Number AEU00394), and must be completed to show when maintenance has been carried out.
6.1.4. Production Record sheets must be completed by the machine setter as a record of the quantity of parts produced including the quantity accepted / rejected as well as wire input records.
6.1.5. Records of all inspection activities must be maintained.
6.1.6. All springs must be fully heat-treated before inspection is performed. The results from these checks will be statistically analysed to establish process capability.
6.1.7. A minimum Cpk. Value as defined on the Works Order Instructions must be achieved in order for the process capability to be considered acceptable.
6.1.8. If at any time the process is found not to be in control, the machine setter will ensure that the machine is stopped, that all affected product is segregated, identified and that, the Section Leader and QA are informed. The machine will not be re-started until necessary actions have been taken to improve the process to at least the required level of capability.

6.2. **Coil Change.**

6.2.1. If a coil change is required, change in accordance with MDI Coil Change (Document Number AEU00436), ensuring that a note is detailed in MeasurLink when the first samples are checked in step 6.4.1.

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6.3. **Start Up.**

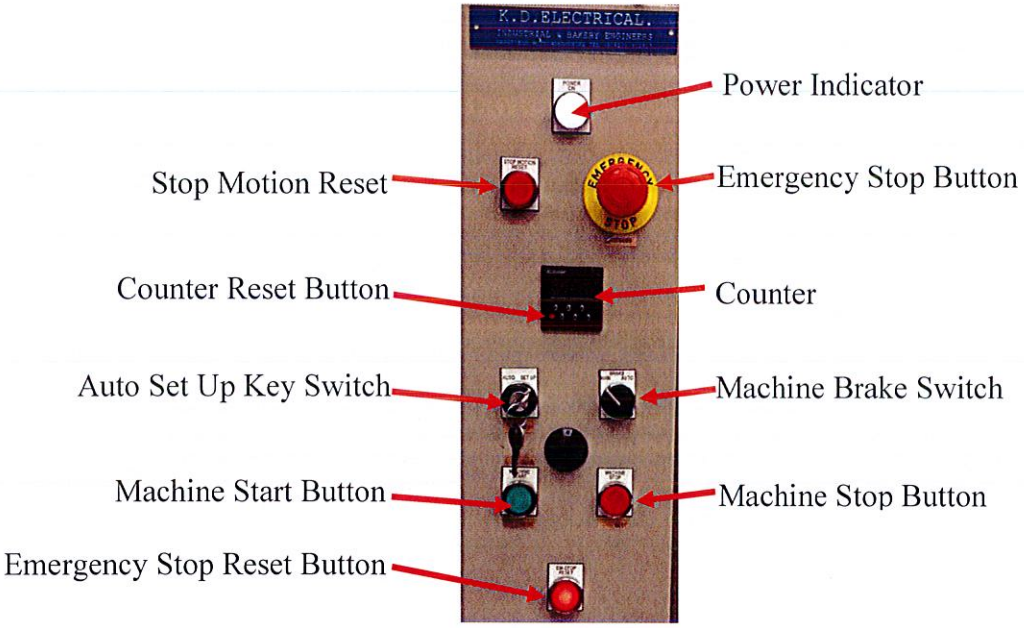

Figure 1: Machine control panel

6.3.1. **Separating Components Made During a Previous Production Run.** The machine setter must ensure that an empty collection bin is positioned at the exit of the heat treatment furnace.

6.3.2. **Final Check Before the Start of Production Run.** The setter must ensure that all required trips and switches are working correctly, reset the counter using the reset button, identified in Figure 1: ensure that all guards and covers are secure and in their correct places.

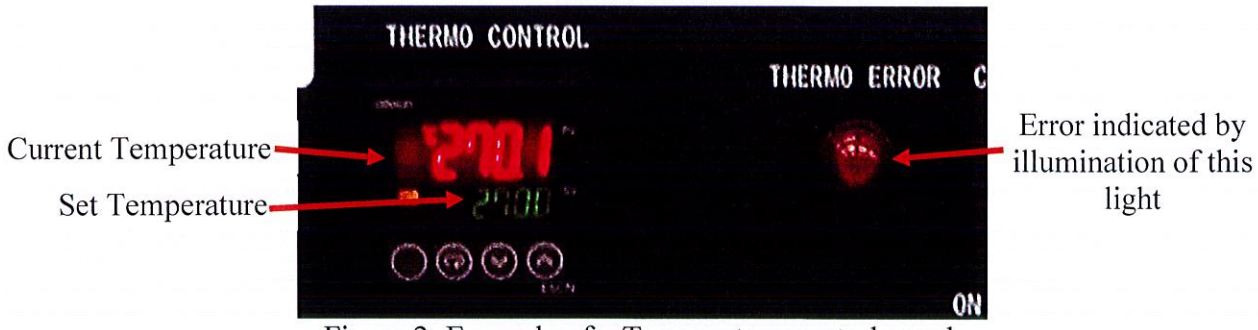

Figure 2: Example of a Temperature control panel.

6.3.3. **Heat Cycle Control Check.** The Setter must ensure that the heat treatment oven is correctly set as detailed on the Works Order Instructions.

Note: There Are Several Different Types Of Oven Controllers But They All Have The Same Type Of Temperature Controllers, As Shown In Figure 2:

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6.3.4. **Check Lubrication and Retaining Pads.** The Setter must ensure that Lubrication and the Retaining Pads are in good condition and the Lubrication bath is adequately full of distillate fluid. If not rectify in accordance with steps detailed in SOP MDI Coil Change (Document Number AEU00436).

6.3.5. **Check Safety Features.** The Setter must ensure that all guards and covers are secure and in their correct places.

6.3.6. **Component Control.** At this point the setter will assign a Works Order to identify the product that will be produced.

6.4. **Production.**

6.4.1. **First Off Inspection.** Upon starting the machine by use of the Machine Start Button, as shown in Figure 1: the setter will complete a recorded first off inspection of one part to ensure conformity of all specified dimensions after heat treatment as detailed in appropriate SOP Measurement Procedure for Slipping Clutch (Document Number AEU00433), Measurement Procedure for Drum Axle (Document Number AEU00434) or Measurement Procedure for Drive Wheel Support Spring (Document Number AEU00435).

Note: Line clearance is required after a first off inspection. This includes first off inspections after coil changes, tool changes or a machine reset.

6.4.2. **SPC Check.** Throughout the production run the Setter will complete and record inspections of all specified critical features at the frequency specified on the Works Order Instructions sheet. All springs must be fully heat-treated before inspection is performed, Using appropriate SOP Measurement Procedure for Slipping Clutch (Document Number AEU00433), Measurement Procedure for Drum Axle (Document Number AEU00434) or Measurement Procedure for Drive Wheel Support Spring (Document Number AEU00435) as a reference. The results from these checks will be statistically analysed to establish process capability. A minimum Cpk. value as defined on the Works Order Instruction must be achieved in order for the process capability to be considered acceptable.

6.4.3. **Process Control.** If at any time the process is found not to be in control, the machine setter will ensure that the machine is stopped, that all affected product is segregated and identified using the procedure outlined in SOP MDI Electrical Failure Furnace (Document Number AEU00227), the Section Leader and QA are to be informed. The machine will not be re-started until necessary actions have been taken to improve the process to at least the required level of capability. A line clearance is required after investigation of non-conforming product.

6.4.4. **Check Correct Carousel Rotation.** The setter will ensure that the carousel is set to index to the next collection bin at the correct frequency by ensuring the correct quantity of components are in each collection bin taken from the carousel.

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6.4.5. **Print Labels.** At a time before the competition of the production run, before the any secondary operations commence, print labels in accordance with SOP Label Preparation (Document Number AEU00437).

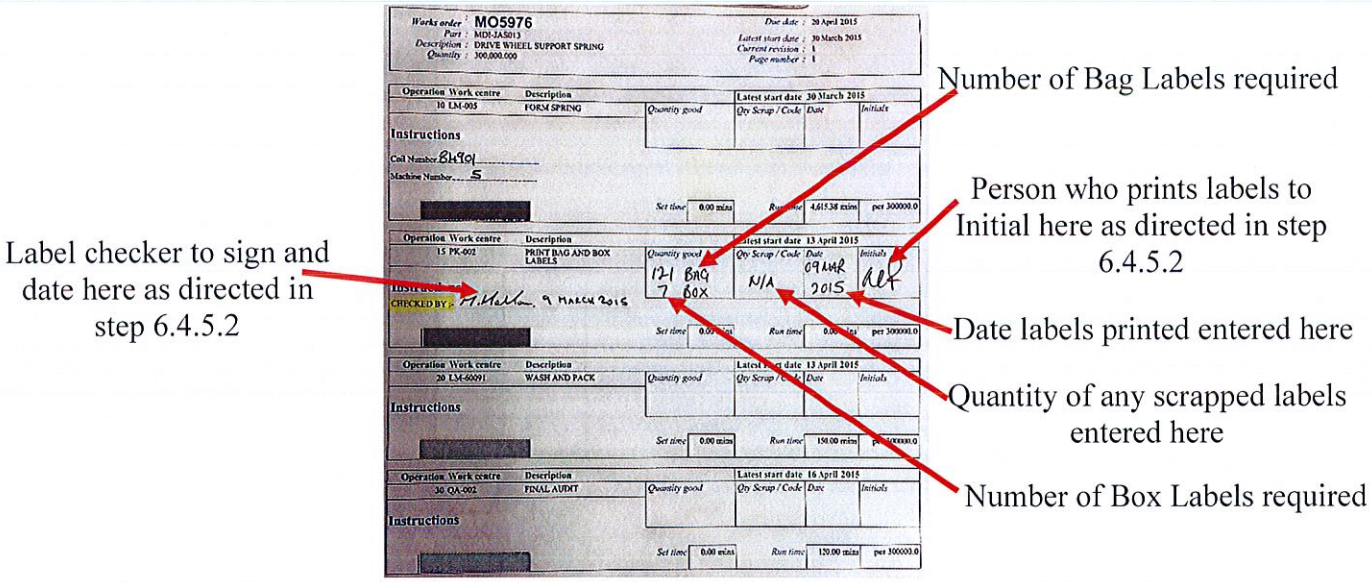

Figure 3: Example of a Works Order Instruction showing the location of information.

6.4.5.1. **Checking Against Work Order Instruction.** The operator is responsible for ensuring that the information on the Works Order Instruction and the label correspond exactly.

6.4.5.2. **Sign Work Order Instruction.** Once satisfied that the labels are correct, the additional labels are attached to the back of the Works Order Instruction, which is then initial and counter signed by a different competent person as evidence of acceptance, as shown in Figure 3: If the operator is not satisfied that the labels are correct, QA are to be informed.

Note: Ensure That The Labels Are Kept With The Components At All Times.

6.4.6. **Component Control.** When the batch is completed the setter will remove all accepted product from the machine. At all times the parts must be identified by the Works Order Instruction number.

6.4.7. **When to Weigh Count.** Weigh counting into required bag quantities is completed at the end of each shift until the quantity indicated on the Works Order Instruction is achieved, as described in SOP MDI Weigh Count & Packing (Document Number AEU00056).

6.4.8. **Sieve Components:** If specified on the Works Order Instructions, once a full batch quantity has been produced, Sieve in accordance with MDI Particulate Separation (Document Number AEU00053). Ensuring that at all times the parts must be identified by the Works Order Instructions number.

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6.4.9. **Wash and Pack Components**. After components have progressed through all required production processes and packed into the final bag quantities, they are to be washed in the Ultrasonic Wash plant and then immediately packed as described in SOP MDI Ultrasonic Washing & Packing (Document Number AEU00054). Ensuring that at all times the parts must be identified by the Works Order Instructions number.

6.4.10. **Electrical or Oven Failure**. If at any time during production either there is an electrical failure lasting longer than one minute or a fault with the oven maintaining the correct temperature, indicated by the illumination of the 'Stop Motion Reset' light as shown in Figure 1: or the 'Thermo Error' light as shown in Figure 2: Follow procedure outlined in SOP MDI Electrical Failure Furnace (Document Number AEU00227).

6.5. **Clean Down.**

6.5.1. **End Forming Process.** At the end of each shift the coiling machine is stopped, either by use of the Machine Stop Button or by the required component count being reached by the counter, as shown in Figure 1:

6.5.2. **Clean Machine.** The face of the machine is cleaned with pressurised air to ensure that it is free of springs from the completed batch.

Note. Safety Glasses Must Be Worn When Using The Compressed Air To Clean.

6.5.3. **Control Components.** All collection bins will be fully emptied of components, weigh counted as per MDI Weigh Count SOP (Document Number AEU00056), then cleaned with pressurised air.

6.5.4. **Update Log.** The production information is recorded by the machine setter on the Machine Log (Document Number AEU00258).

6.6. **Paperwork.**

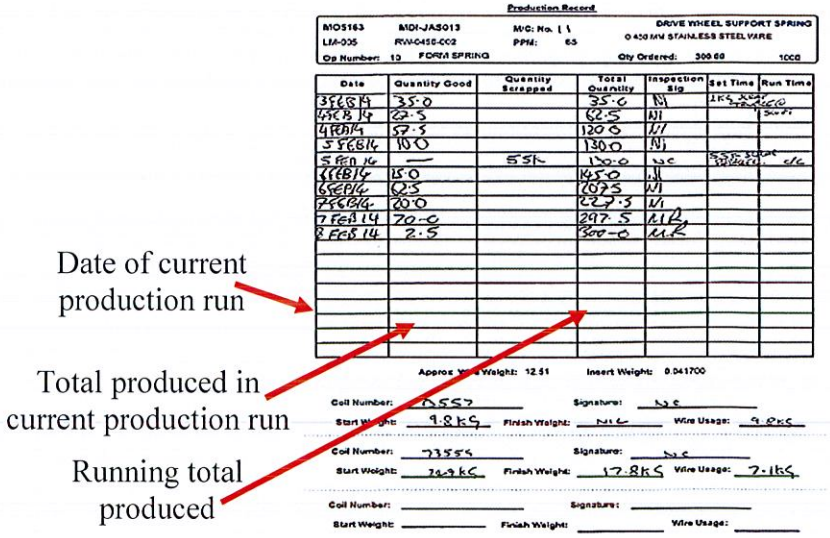

Figure 4: Example of a completed Production Record.

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6.6.1. **Production Record.** At the end of each shift the Production Record is update with total number of components made / scrapped. Upon completion of number of components specified on the Works Order Instruction in addition to the total number of components made / scrapped information the wire usage is also entered and signed off.

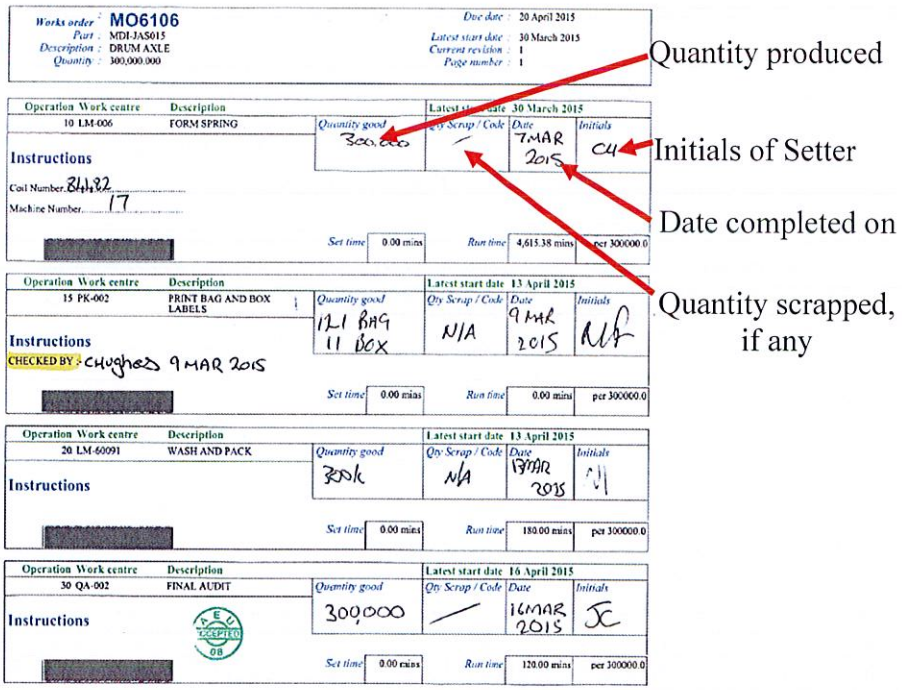

Figure 5: Example of a completed Works Order Instruction.

6.6.2. **Works Order Instruction.** Upon completion of number of components specified on the Works Order Instruction, enter the date completed, the quantity produced, the number of any scrapped off and then sign to indicate compliance with the specification.