PRO AUTOMACHINES
PROCEDURE QUALIFICATION

Profile Introduction.

PRO AUTOMACHINES. is thankful to you for choosing its 'STEPPER WRAPROUND LABELING MACHINE'. It is very essential to go through & follow the instructions, very carefully, in this manual for a trouble-free operation of this machine.

Buyer Details

Clients Name **: DUNCAN HEALTHCARE PRIVATE LIMITED**

Machine Manufacturer

Machine Manufacturer	:	PRO AUTOMACHINES.
Address	**:**	Factory Address: - Kumbar pada, Near Waghoba Mandir, Virar(E), PALGHAR-401303. Mobile No :-8591264010
Machine Name	:	STEPPER WRAPROUND LABELING MACHINE.
Machine Serial No.	:	PRO01
Contact Person	:	Mr. Adesh Joshi.

Table of Contents

Prepared By

Name	**Adesh Joshi.**
Profile Designation	**Director**
Role	**Writing out PQ protocol For Duncan Healthcare Pvt.Ltd.**
Responsibilities	**Writing out PQ protocol for Duncan Healthcare Pvt.Ltd. Furnishing information of Duncan Healthcare Pvt.Ltd. PQ document.**

Pre-Approval:

M/s. PRO AUTOMACHINES

	Name	Designation	Signature	Date
Prepared By.	**Adesh Joshi**	**Director**		
Reviewed By				

M/s. Duncan Healthcare Pvt.Ltd.

	Person Name	Designation	Signature	Date
Reviewed By.				
Reviewed By.				
Approved By.				

1. Objective:

To establish the documented evidences for the qualification of machine design as per the user requirement specifications (URS).

2. Scope:

The scope of this document is limited to the Design Qualification for Stepper PLC Wraproud Labeling Machine. The support utilities required for the functioning of the machine are not within the scope of this qualification. The equipment shall meet all the requirements mentioned in the URS.

3. Responsibilities

The following responsibilities are shared by
i) **Duncan Healthcare Pvt.Ltd.**

Responsibilities of M/s. PRO AUTOMACHINES are:

- To design, engineer and provide the complete technical details of the equipment pertaining to its design qualification.
- Machine G.A drawing.
- Component details, List of brought out items, and their make, model & quantity.
- Details of Utilities.
- Material of construction (MOC) of components.

Responsibilities of Duncan Healthcare Pvt.Ltd. are:

- To provide the URS for the equipment.
- To view the Design qualification and give its approval.

4. Machine Description

Our Labeling Machine is designed for applying the labeling on Bottles. The machine is an assembly with a SS structure label applicator at the Back side of the machine. Stepper Motor on the label applicator activates the unit for unwinding & rewinding process.

It is very simple to operate and have maximum accuracy. The operator simply has to feed the operating parameters in the HMI and press the start push button to start the machine operation.

The machine is well equipped with a single-phase control panel consisting electrical as well as electronics components. All components are highly over rated and necessary safety devices are employed to protect both the operator and the equipment.

The overall machine tolerance is +/-1mm at variable speed.

Safety features are provided in the machine, which are as per the GMP standards and is in compliance with set industrial standards

The brief description of the machine is described in the functional description,

Salient Features:

- All Contact parts are of SS 304.
- Various assemblies can be removed for cleaning easily.
- Simple operation and easy maintenance.
- Operator Panel for easy operation.

5. Indented and prohibited use of the System:

Intended Use:
The machine is designed to perform for labeling on Bottle.

Prohibited Use:
Any other use of the Machine will be deemed to be not in accordance with its Design and specified purpose.

6. Safety Features on the Machine.

Sr. No.	Description
1	Emergency Switch on the Operator Panel to stop the machine in any emergency condition.
2	Ferruling on the cable for proper traceability.
3	MCBs inside the Control Panel to trip off if any short circuit occurs.
4	Grommets provide inside the panel to avoid cut hazard to the cables.

7.Technical Specification.

Sr. No.	Description	
	Commercial Data	
1	Machine Manufacturer	PRO AUTOMACHINES
2	Machine Name	Stepper PLC Wraproud Labeling Machine.
3	Year / Month of Equipment Mfg.	DEC 2023.
	Mechanical Data	
1	Machine dimension	As per G.A drawing
2	Approx. Weight	300 Kg Approximately
3	Contact Parts	SS 304/Aluminum
	Electrical Data	
1	Machine Voltage	230 Voltage AC, Single Phase, 50 Hz.
2	Customer Power Plant Supply	230 Voltage AC, Single Phase, 50 Hz.
3	Main Cable Size	1.5 SQ MM 3 Core

8.Utilities Required

Electrical Supply
Machine Voltage
230 Voltage AC, Single Phase, 50 Hz.
Main Cable Size for all the Machine : 1.5 SQ MM 3 Core

9.Operational Sequence.

1) Feed the label roller inside the roll holder.

2) Ensure that the roller core is locked firmly with the core lock provided on thespool.

3) Place the upper spool on the web roller.

4) Follow the label path as per the Drag. Placed on the label applicator.

5) Switch ON the Supply Mains from the Main Junction Box to active the Operator Panel.

6) Regulate the Main Supply Selector Switch towards ON position, this will activate
Machine & the HMI starts displaying the Welcome Screen.

7) Press the RUN Key to view the Main Menu Screen. Run key highlighted with redrectangle.

8) Press the START push button to start the Machine Operation.
As soon as the Start Button is pressed the following Assemblies gets activated.
Conveyor ------ Spacer Unit ---------- Wraproud Unit.

9) Start feeding the bottle on the running conveyor. The spacer unit creates gapbetween the fed bottles for proper uniformity.

10) After created by specific gap in bottle rows it will passes to the Labeler Unit.

11) But before the bottles are sensed by the bottle presence sensor, this sensor signals the PLC, further the PLC commands the Steeper Motorfor activation.

12) The Rubber roller which is activated pulls the label strip from the roller.

13) The label presence sensor senses the presence of label.

Note:
If there is no label sensed, the steeper motors command the label applicator torotate twice for bypassing the labels. And absence of more labels will stop the spacer unit and there will be alarm of Paper Break.

14) The peeler plate peels the release paper from the label and allows the label toget paste on the moving bottles.

15) The label is firmly pressed on the bottles by the wrapround unit.

10.Operational Qualification Test.

Sr. No.	Description		
1	**Machine Power ON Test**		
	Purpose	To check the machine during machine power ON condition.	
	Method	Connect the Main electrical power supply; it should be 230 V AC, Single Phase, 50 Hz. Switch ON the Isolator Switch and check machine performance.	
	Acceptance Criteria	PRO AUTOMACHINES Welcome Screen will appear on HMI.	

Remarks:

Sr. No.	Description		
2	**Three level password Verification Test.**		
	Purpose	To check the three-level access password (available only numeric key) provisions for operator level, supervisor level & Admin level are provided to machine.	
	Method	1. Go to HMI Control screen. 2. Enter the user's name and access password foroperator level & press login key. 3. Main menu screen will appear. 4. Checked operator level allowed access. 5. Press HMI LOGOUT button. 6. Go to HMI Control screen. 7. Enter the user's name and access password forSupervisor level & press login key. 8. Main menu screen will appear. 9. Checked supervisor level allowed access. 10. Press HMI LOGOUT button. 11. Go to HMI Control screen. 12. Enter the user's name and access password forAdmin level & press login key. 13. Main menu screen will appear. 14. Checked Admin level allowed access. 15. Press HMI LOGOUT button.	
	Acceptance Criteria	Login provisions for operator, supervisor & Admin are provided and allowed password to access are working as per logic.	

Remarks:

Sr. No.	Description		
3	**Recipe selection & Parameter Value editing Test.**		
	Purpose	To check the recipe selection & parameter value editing in allowable access.	
	Method	1. Go to welcome screen. 2. Enter user name and password only supervisor & Admin level and press enter key. 3. Press recipe Button. 4. For creating new recipe press new recipe button and edit the name in popup window. 5. After editing name of new recipe user can change values in recipe screen as well as in setting screen.	
	Acceptance Criteria	1. Required recipe name can be edited & load. 2. Recipe can be loaded as desired.	

Remarks:

Sr. No.	Description		
4	**Labeling Test**		
	Purpose	To check the machine performance during labeling operation.	
	Method	Check all the interlocks are fulfilled to start the machine. Ensure that the Label roller is placed on the holder as per the label path Ensure all the Recipe parameters are set in the HMI Load the Bottle manually on the infeed conveyor. Press the Run Key from the Welcome Screen Press Conveyor OFF Key Press Spacer OFF Key Press Wraparound OFF Key Press Labeler OFF Key Now press Start OFF key to start the machine.	
	Acceptance Criteria	Check there is proper labeling happening on Bottles and there is no damage of labels during label application on Bottles and also labels skew within tolerance of +/- 1mm	

Remarks:

Sr. No.	Description		
5	**Emergency Stop Alarm Test**		
	Purpose	To check the Emergency after activating.	
	Method	Keep machine in the running condition and apply Emergency Stop Switch.	
	Acceptance Criteria	All the machine movements are ceased automatically. Rotate it in clockwise, followed by the Reset Key on the HMI and press start button after that flush function on and start the machine operation.	

Remarks:

Sr. No.	Description		
6	**Conveyor VFD Communication Error Test.**		
	Purpose	To check the Conveyor VFD Communication error alarm.	
	Method	Keep the machine in running condition. Manually Trip the Conveyor MCB. Check The Machine Performance.	
	Acceptance Criteria	The Machine will stop & Conveyor VFD Communication Error Alarm generated on HMI.	

Remarks:

Sr. No.	Description		
7	**Spacer VFD Communication Error Test.**		
	Purpose	To check the Spacer VFD Communication error alarm.	
	Method	Keep the machine in running condition. Manually Trip the Spacer MCB. Check The Machine Performance.	
	Acceptance Criteria	The Machine will stop & Spacer VFD Communication Error Alarm generated on HMI.	

Remarks:

Sr. No.	Description		
8	**Wraproud VFD Communication Error Test.**		
	Purpose	To check the Wraproud VFD Communication error alarm.	
	Method	Keep the machine in running condition. Manually Trip the Wraproud MCB. Check The Machine Performance.	
	Acceptance Criteria	The Machine will stop & Wraproud VFD Communication Error Alarm generated on HMI.	

Remarks:

Sr. No.	Description		
9	**Labeler Stepper Drive Error Test.**		
	Purpose	To check the Labeler Stepper Drive Error alarm.	
	Method	Keep the machine in running condition. Manually Trip the Labeler stepper drive MCB. Check The Machine Performance.	
	Acceptance Criteria	The Machine will stop & Labeler Stepper Drive Error Alarm generated on HMI.	

Remarks:

Sr. No.	Description		
10	**Label roll break fault (Labeler) Spacer Stop Test.**		
	Purpose	To check the spacer will stop operation when there is Label roll break fault.	
	Method	Keep the machine in running condition. Remove the two labels from the label strip after label sensor. Load the Bottles for labeling and check the machine Performance.	
	Acceptance Criteria	The Spacer will stop and indicate Label Roll Break Fault (Labeler) Alarm on HMI.	

Remarks:

11.Labeling Machine Alarm List.

Sr. No.	Alarm list	Verified (Yes/No)
1	Emergency Stop Alarm	
2	Conveyor VFD Communication Error	
3	Spacer VFD Communication Error	
4	Wrapround VFD Communication Error	
5	Labeler Stepper Drive Error	
6	Label Roll Break Fault (Labeler)	