Logo <insert project name>

FAT

Factory acceptance test

Project name	<insert project name>
Project number	<insert project number>

Contents

1. Document history

Revision	Date	Compilation	Changes
1.0.0	18.Apr.2017	John Doe	First version

1.1. Glossary

CPL	Change part list
EBR	Electronic Batch Record
EC	European conformity declaration
FAT	Factory acceptance test
FS	Functional specification
FSC	Function specification and configuration document
GUI	Graphical User Interface
HDS	Hardware design specification
HMI	Human-machine interface
IQ	Installation qualification
MPO	Maintenance Plan Overview
OQ	Operational qualification
PCP	Parts in contact with product
Recipe	Inspection setting
SAT	Site acceptance test
SDS	Software design specification
SVS	Software version specification
URS	User requirement specification
WPL	Wear part list

1.2. Qualification team identification

List of people involved in qualification session execution				
1	Print name:		Signature:	
	Company:		Initials:	
	Function:		Role:	☐ Executioner ☐ Witness
2	Print name:		Signature:	
	Company:		Initials:	
	Function:		Role:	☐ Executioner ☐ Witness
3	Print name:		Signature:	
	Company:		Initials:	
	Function:		Role:	☐ Executioner ☐ Witness
4	Print name:		Signature:	
	Company:		Initials:	
	Function:		Role:	☐ Executioner ☐ Witness
5	Print name:		Signature:	
	Company:		Initials:	
	Function:		Role:	☐ Executioner ☐ Witness
6	Print name:		Signature:	
	Company:		Initials:	
	Function:		Role:	☐ Executioner ☐ Witness

7	Print name:		Signature:	
	Company:		Initials:	
	Function:		Role:	☐ Executioner ☐ Witness

8	Print name:		Signature:	
	Company:		Initials:	
	Function:		Role:	☐ Executioner ☐ Witness

9	Print name:		Signature:	
	Company:		Initials:	
	Function:		Role:	☐ Executioner ☐ Witness

10	Print name:		Signature:	
	Company:		Initials:	
	Function:		Role:	☐ Executioner ☐ Witness

11	Print name:		Signature:	
	Company:		Initials:	
	Function:		Role:	☐ Executioner ☐ Witness

12	Print name:		Signature:	
	Company:		Initials:	
	Function:		Role:	☐ Executioner ☐ Witness

2. Introduction

2.1. Scope

This document includes acceptance tests to check critical devices and functions of the machine. The acceptance tests are to assure that:

- The equipment is built in accordance with engineering and vendor specifications.
- The equipment operates in compliance with the functional description.
- The documentation complies to the “as-built” status.

2.2. Test instruction

1. Before starting ensure all required documents for verification are available.
2. If tests require verification of documents: this must be marked on the approved document and this marked document must be attached to the completed test protocol.
3. Execution of the test must be witnessed by Customer’s representative.
4. Executioner and witness signs at completion of each test section.
5. Record any deficiency found in the Deficiency list.

3. Installation qualification tests

The Installation qualification tests are grouped in the following chapters:

Chapter tag	Chapter title
IQ T1	Documentation verification
IQ T2	Safety devices
IQ T3	Media supply
IQ T4	Software
IQ T5	Material and roughness checks
IQ T6	Additional checks

3.1. Documentation verification

Test #	Test name / Test description	Acceptance criteria / Expected test result	Actual result	Pass/Fail deficiency #	Executed / Verified by (Initials, date)
IQ T1.1	**Equipment drawings verification** This test is performed to verify if equipment drawings and equipment dimensions are accurate.	Drawings must match with the equipment. Drawing dimensions should be within ± 3% of the measurement taken.	Tick the relevant box.	If one or more results are “No” then enter deficiency number(s): Test # - Deficiency #.	Executed: Verified:
		Layout diagram	☐ Yes ☐ No Attachment #: _____		

3.2. Safety devices

Test #	Test name / Test description	Acceptance criteria / Expected test result	Actual result	Pass/Fail deficiency #	Executed / Witnessed by (Initials, date)
IQ T2.1	**Safety devices check** Check the presence of safety devices. Take Technical specification of safety devices and check the presence of safety devices listed in the document. Mark with green if components are present and with red if components are not present. Attach the signed document.		Tick the relevant box.	If one or more results are “No” then enter deficiency number(s): Test # - Deficiency #.	Executed: Witnessed:
		Safety devices are present.	☐ Yes ☐ No		

3.3. Media supply

Test #	Test name / Test description	Acceptance criteria / Expected test result	Actual result	Pass/Fail deficiency #	Executed / Witnessed by (Initials, date)
IQ T3.1	**Compressed air** The compressed air supply is checked.	Compressed air supply value is in the specified range.	Tick the relevant box.	If one or more results are “No” then enter deficiency number(s): Test # - Deficiency #.	Executed: Witnessed:
		Compressed air supply value is p= 6 – 10 bar	Compressed air supply value is in specified range. p= _____bar ☐ Yes ☐ No		

3.4. Software

3.5. Material and roughness checks

Test #	Test name / Test description	Acceptance criteria / Expected test result	Actual result	Pass/Fail deficiency #	Executed / Witnessed by (Initials, date)
IQ T5.1	**Parts in contact with products** The surface roughness for parts in contact with products must allow cleanability. A surface roughness for metallic parts of Ra<0.8 is required. Synthetic materials in contact with product must be GMP compliant and resistant to all other materials used (media, cleaning agents and disinfectants). Take PCP document and check if metalic are listed and certificates are attached.		Tick the relevant box.	If one or more results are “No” then enter deficiency number(s): Test # - Deficiency #.	Executed: Witnessed:
		PCP document lists metallic parts with certificates.	☐ Yes ☐ No Attachment #: _____		

3.6. Additional checks

Test #	Test name / Test description	Acceptance criteria / Expected test result	Actual result	Pass/Fail deficiency #	Executed / Witnessed by (Initials, date)
IQ T6.1	**Check the of scales for reproducibility of settings** Visually check the presence of scales for mechanical parameters described in User list of parameters.	Visual check: scales are provided for all mechanical parameters.	Tick the relevant box. ☐ Yes ☐ No	If one or more results are "No" then enter deficiency number(s): Test # - Deficiency #.	Executed: Verified:

3.7. Comments for Installation qualification tests

Comments for Installation qualification tests

Signature for comments		
Executed: Name:	Signature:	Date:
Witnessed: Name:	Signature:	Date:

4. Operation qualification tests

The Operation qualification tests are grouped in the following chapters:

Chapter tag	Chapter Title
OQ T1	Safety functions
OQ T2	Modes of operation
OQ T3	Production requirement
OQ T4	Alarms
OQ T5	Additional operations and functions checks

4.1. Safety functions

<table>
<tr><th>Test #</th><th>Test name / Test description</th></tr>
<tr><td>OQ
T1.1</td><td>
Safety at system failure & Main switch check
In case of power loss, the system must be protected in the following priority and the likelihood of damage must be minimized:

People and Environment
Equipment
Product

This test is done by switching off the machine.
<table>
<tr><th>Test procedure</th></tr>
<tr><td>
<table>
<tr><th>Step #</th><th>Step description</th><th>Tick if done</th></tr>
<tr><td>1.</td><td>Start the machine in operation mode.</td><td>☐</td></tr>
<tr><td>2.</td><td>Switch off the machine by switching turning off the main switch.</td><td>☐</td></tr>
<tr><td>3.</td><td>Switch on the machine by turning the main power switch to ON. Machine starts-up.</td><td>☐</td></tr>
</table>
</td></tr>
<tr><td>
<table>
<tr><th>Acceptance criteria</th><th colspan="2">Actual result</th></tr>
<tr><td>1. Machine completely stops after switching off the main switch.</td><td>☐ Yes</td><td>☐ No</td></tr>
<tr><td>2. Machine starts-up after turning main power switch to ON but does not start to inspect automatically.</td><td>☐ Yes</td><td>☐ No</td></tr>
</table>
</td></tr>
<tr><td>
<table>
<tr><th>Pass/Fail deficiency #</th></tr>
<tr><td>☐ Pass ☐ Fail, deficiency #: _____</td></tr>
</table>
</td></tr>
<tr><td>
<table>
<tr><th>Executed by (Initials, date)</th><th>Witnessed by (Initials, date)</th></tr>
<tr><td></td><td></td></tr>
</table>
</td></tr>
</table>
</td></tr>
</table>

4.2. Modes of operation

4.3. Production requirement

Test #	Test name / Test description
OQ T3.1	**Machine speed** Machine output > 120 units / minute

Test procedure

Step #	Step description	Tick if done
1.	Test set-up: ▪ Write down the product name used for this test: ▪ _____ ▪ Recipe used: _____ ▪ Set the machine as described in the recipe. ▪ Fill the input container with approximately 2000 pieces of test product.	☐
2.	Set speed parameter to maximum value: _____	☐
3.	Start the machine in operation mode.	☐
4.	Wait for the machine to achieve maximum speed.	☐
5.	Make print screen from GUI, where speed is displayed.	☐
6.	Print the print screen, sign and attach it to the document: ▪ Attachment #: _____	☐
7.	Restore the parameter(s) to original value: ▪ Speed parameter	☐

Acceptance criteria	Actual result	
Inspection speed of test product is more than 120 units / minute	☐ Yes	☐ No

Pass/Fail deficiency #

☐ Pass ☐ Fail, deficiency #: _____

Executed by (Initials, date)	Witnessed by (Initials, date)

4.4. Alarms

Test #	Test name / Test description
OQ T4.1	**Alarm #001 test** Vacuum system failure detected!

Test procedure

Step #	Step description	Tick if done
1.	Test set-up: ▪ Remove test product from the machine. ▪ Recipe used: _____ ▪ Set the machine for test as described in loaded setting description.	☐
2.	Run the machine in operation mode.	☐
3.	Simulate vacuum pump failure by turning off vacuum pump main switch.	☐
4.	In case of vacuum system failure, machine stops and the Alarm #001 is displayed.	☐
5.	Confirm the alarm.	☐
6.	Switch on vacuum pump main switch.	☐
7.	Vacuum pump starts.	☐

Acceptance criteria	Actual result	
In case of vacuum system failure, machine stops and the Alarm #001 is displayed.	☐ Yes	☐ No

Pass/Fail deficiency #

☐ Pass ☐ Fail, deficiency #: _____

Executed by (Initials, date)	Witnessed by (Initials, date)

4.5. Additional operations and functions checks

Test #	Test name / Test description		
OQ T5.1			
	Test procedure		
	Step #	**Step description**	**Tick if done**
	1.	▪	☐
	2.	▪	☐
	Actual result		
		☐ Yes	☐ No
		☐ Yes	☐ No
	Pass/Fail deficiency #		
	☐ Pass ☐ Fail, deficiency #: _____		
	Executed by (Initials, date)	**Witnessed by (Initials, date)**	

4.6. Comments for Operation qualification tests

Comments

Signature for comments		
Executed: Name:	Signature:	Date:
Witnessed: Name:	Signature:	Date:

5. List of appendices

5.1. Appendix 1 – Equipment list

5.2. Appendix 2 – Test material list

5.3. Appendix 3 – Attachment list

5.4. Appendix 4 – Deficiency list