

L o g o	<insert project name>	Page 1 / 8
---------	-----------------------	------------

User requirement specifications and design qualifications

Project name	
Project number	

Name	Function	Signature
	Qualification coordinator (author)	
	Engineering	
	HSE	
	User Lead	

L o g o	<insert project name>	Page 2 / 8
---------	-----------------------	------------

TABLE OF CONTENTS

1	INTRODUCTION	3
1.1	DEFINITIONS AND ABBREVIATIONS	3
1.2	URS TYPE	3
2	USER REQUIREMENT SPECIFICATIONS	4
2.1	TECHNICAL SAFETY STANDARDS AND REQUIREMENTS ON OCCUPATIONAL SAFETY	4
2.2	PROCESS, PRODUCT AND FUNCTIONAL REQUIREMENTS.....	5
2.3	GENERAL REQUIREMENTS	6
2.3.1	<i>Material standards</i>	6
2.3.2	<i>ERES requirements</i>	6
3	SUMMARY ASSESSMENT	7
3.1	COMMENTS OF SUPPLIERS	7
3.2	DQ COMMENTS	8

1 Introduction

Introduction is used for the following topics.

- Aim of the document
- Project goals
- Instructions on how to use document
- Definitions and Abbreviation
- URS types definitions

1.1 Definitions and Abbreviations

CFR	Code of Federal Regulation (USA)
cGMP	Current Good Manufacturing Practice
DQ	Design Qualification
EHS	Environmental, Health & Safety
EN	European Standard
ERES	Electronic Records and Signatures
EU	European Union
FAT	Factory Acceptance Test
FDA	Food and Drug Administration (USA)
FS	Functional Specification:
GAMP	Good Automated Manufacturing Practice
HMI	Human Machine Interface → Operator control
HEPA	High Efficiency Particulate Air
IQ	Installation Qualification
OQ	Operational Qualification / Operational Qualification
PQ	Performance Qualification
Ra	Roughness
SAT	Site Acceptance Test / commissioning at the customer
SOP	Standard Operating Procedure
URS	User Requirement Specification / specifications

1.2 URS type definitions

The URS type distinguishes between the following two types of requests:

- M Mandatory: Presupposes the fulfillment of the requirement for a contract.
O Optional: Provides a wish request, nevertheless may have an impact on a contract.

Logo	<insert project name>	Page 4 / 8
------	-----------------------	------------

2 User requirement specifications

2.1 Technical Safety Standards and requirements on Occupational Safety

User Requirement Specification <i>(prepared by the USER)</i>		Functional Specification <i>(answered by the SUPPLIER)</i>		DQ – Evaluation of FS <i>(prepared by the USER)</i>
URS type	Requirement	Compliant? (Yes/No)	Comment / Alternative	Comments / conclusions
M	Compliance with the Machinery Directive in accordance with EC Machinery Directive 2006/42/ EC			
M	Function, design and operation of the system do not result in injury to people and machine - no joints - no sharp corners			

Logo	<insert project name>	Page 5 / 8
------	-----------------------	------------

2.2 Process, product and functional requirements

User Requirement Specification <i>(prepared by the USER)</i>			Functional Specification <i>(answered by the SUPPLIER)</i>		DQ – Evaluation of FS <i>(prepared by the USER)</i>
URS- No.	URS type	Requirement	Compliant? (Yes/No)	Comment / Alternative	Comments / conclusions
1.	M	Machine throughput of 120 units per minute.			

Logo	<insert project name>	Page 6 / 8
------	-----------------------	------------

2.3 General requirements

2.3.1 Material standards

User Requirement Specification <i>(prepared by the USER)</i>			Functional Specification <i>(answered by the SUPPLIER)</i>		DQ – Evaluation of FS <i>(prepared by the USER)</i>
URS- No.	URS type	Requirement	Requirement fulfilled? (YES NO)	Comment / Alternative	Rating
2.	M	The surface for direct product contact surfaces does not exceed Ra = 0.8 Be microns.			

2.3.2 ERES requirements

User Requirement Specification <i>(prepared by the USER)</i>			Functional Specification <i>(answered by the SUPPLIER)</i>		DQ – Evaluation of FS <i>(prepared by the USER)</i>
URS- No.	URS type	Requirement	Requirement fulfilled? (YES NO)	Comment / Alternative	Rating
3.	M	The software meets the requirements of 21 CFR Part 11			

