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VALIDATION & QUALIFICATION PACKAGES

ENFLEX
a coesia brand

INDEX

PACKAGES

Qualification and Validation: modular packages of documentation

- Enflex has a **specific team** dedicated to the creation of **validation** documentation and the **qualification of equipment** for GMP environments
- We can also count on the support of **external consulting firms** with extensive experience in the pharmaceutical sector
- We have designed our Validation & Qualification documents in **modular packages**, to meet the simplest to the most complex needs

Basic

Installation Qualification (IQ)

Operational Qualification (OQ)

Plus

Pharma Factory Acceptance Test (FAT)

Site Acceptance Test (SAT)

Installation Qualification (IQ)

Operational Qualification (OQ)

Premium

Qualification Plan (QP)

Pharma Risk Assessment (RA)

Pharma Factory Acceptance Test (FAT)

Site Acceptance Test (SAT)

Installation Qualification (IQ)

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Elite

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Pharma Risk Assessment (RA)

Functional Designs Specifications (FDS)

Hardware Designs Specifications (HDS)

Software Designs Specifications (SDS)

Design Qualification (DQ)

Pharma Factory Acceptance Test (FAT)

Site Acceptance Test (SAT)

Installation Qualification (IQ)

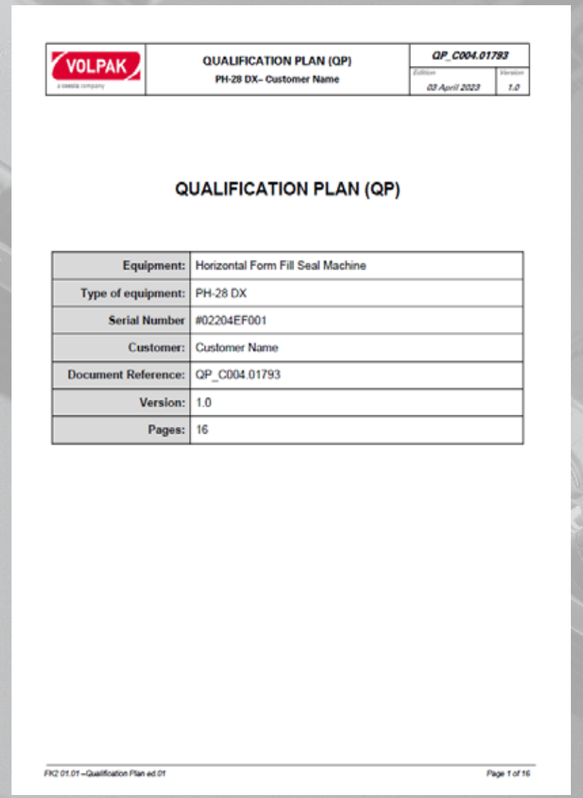
Operational Qualification (OQ)

Qualification Plan (QP)

The purpose of the Qualification Plan (QP) is to provide and define the qualification activities that will be performed during project execution, the responsibilities that correspond to the staff involved and the procedures that must be carried out.

The following information is detailed in the QP:

- Project qualification strategy
- Project qualification documentation structure
- List of qualification tests.
- Methodology (management of deviations and change controls)
- Responsibilities matrix



VOLPAK | QUALIFICATION PLAN (QP) PH-28 DX- Customer Name | QP_C004.01793 | Edition 03 April 2023 | Version 1.0

QUALIFICATION PLAN (QP)

Equipment:	Horizontal Form Fill Seal Machine
Type of equipment:	PH-28 DX
Serial Number	#02204EF001
Customer:	Customer Name
Document Reference:	QP_C004.01793
Version:	1.0
Pages:	16

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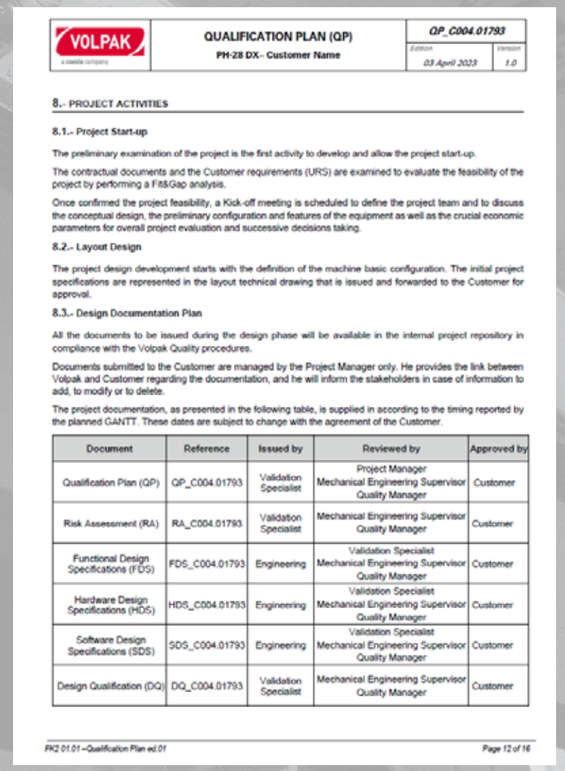

VOLPAK | QUALIFICATION PLAN (QP) PH-28 DX- Customer Name | QP_C004.01793 | Edition 03 April 2023 | Version 1.0

8.- PROJECT ACTIVITIES

8.1.- Project Start-up

The preliminary examination of the project is the first activity to develop and allow the project start-up.

The contractual documents and the Customer requirements (URS) are examined to evaluate the feasibility of the project by performing a Fit&Gap analysis.

Once confirmed the project feasibility, a Kick-off meeting is scheduled to define the project team and to discuss the conceptual design, the preliminary configuration and features of the equipment as well as the crucial economic parameters for overall project evaluation and successive decisions taking.

8.2.- Layout Design

The project design development starts with the definition of the machine basic configuration. The initial project specifications are represented in the layout technical drawing that is issued and forwarded to the Customer for approval.

8.3.- Design Documentation Plan

All the documents to be issued during the design phase will be available in the internal project repository in compliance with the Volpak Quality procedures.

Documents submitted to the Customer are managed by the Project Manager only. He provides the link between Volpak and Customer regarding the documentation, and he will inform the stakeholders in case of information to add, to modify or to delete.

The project documentation, as presented in the following table, is supplied in according to the timing reported by the planned GANTT. These dates are subject to change with the agreement of the Customer.

Document	Reference	Issued by	Reviewed by	Approved by
Qualification Plan (QP)	QP_C004.01793	Validation Specialist	Project Manager Mechanical Engineering Supervisor Quality Manager	Customer
Risk Assessment (RA)	RA_C004.01793	Validation Specialist	Mechanical Engineering Supervisor Quality Manager	Customer
Functional Design Specifications (FDS)	FDS_C004.01793	Engineering	Validation Specialist Mechanical Engineering Supervisor Quality Manager	Customer
Hardware Design Specifications (HDS)	HDS_C004.01793	Engineering	Validation Specialist Mechanical Engineering Supervisor Quality Manager	Customer
Software Design Specifications (SDS)	SDS_C004.01793	Engineering	Validation Specialist Mechanical Engineering Supervisor Quality Manager	Customer
Design Qualification (DQ)	DQ_C004.01793	Validation Specialist	Mechanical Engineering Supervisor Quality Manager	Customer

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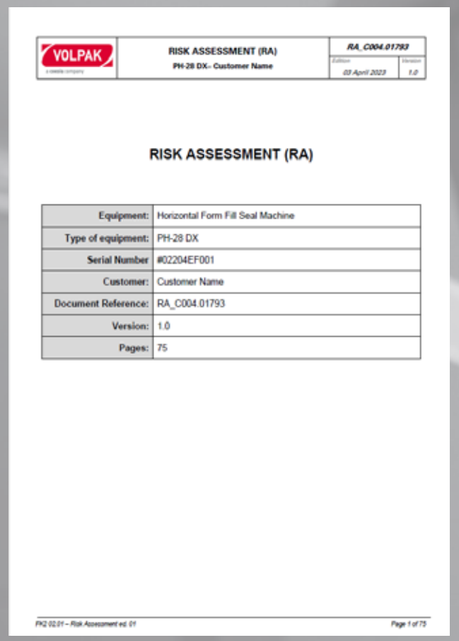
Pharma Risk Analysis (RA)

Risk analysis methodology enables assessment of equipment features from the perspective of GMP compliance. Assessment is carried out on all aspects that may affect product quality, patient safety and/or data integrity.

The FMEA (Failure Mode and Effects Analysis) method is used to classify the various parts of the machine, analyse potential failures and their consequences, assess the likelihood and detectability of the failure and the severity of the consequence. These three assessments reveal a risk rate which, if properly tabulated, can indicate the qualification actions required to mitigate the risk.



VOLPAK — RISK ASSESSMENT (RA) — PH-28 DX- Customer Name — RA_C004.01793 — Edition 03 April 2023 — Version 1.0

RISK ASSESSMENT (RA)

Equipment:	Horizontal Form Fill Seal Machine
Type of equipment:	PH-28 DX
Serial Number	#02204EF001
Customer:	Customer Name
Document Reference:	RA_C004.01793
Version:	1.0
Pages:	75

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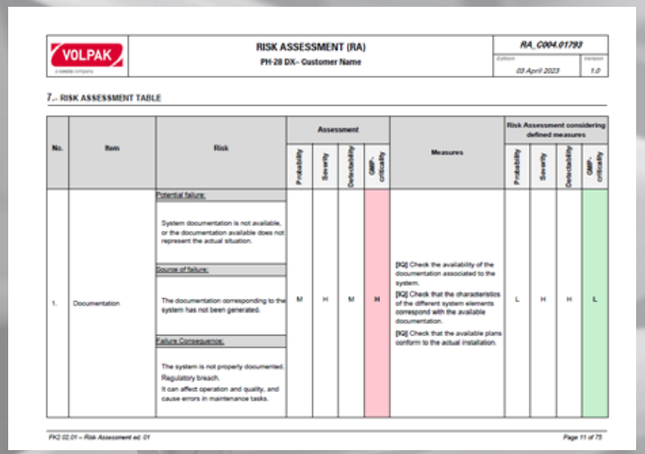

VOLPAK — RISK ASSESSMENT (RA) — PH-28 DX- Customer Name — RA_C004.01793 — Edition 03 April 2023 — Version 1.0

7.- RISK ASSESSMENT TABLE

No.	Item	Risk	Assessment: Probability	Assessment: Severity	Assessment: Detectability	Assessment: GMP- criticality	Measures	Risk Assessment considering defined measures: Probability	Severity	Detectability	GMP- criticality
1.	Documentation	Potential failure: System documentation is not available, or the documentation available does not represent the actual situation. Source of failure: The documentation corresponding to the system has not been generated. Failure Consequence: The system is not properly documented. Regulatory breach. It can affect operation and quality, and cause errors in maintenance tasks.	M	H	M	H	[IQ] Check the availability of the documentation associated to the system. [IQ] Check that the characteristics of the different system elements correspond with the available documentation. [IQ] Check that the available plans conform to the actual installation.	L	H	H	L

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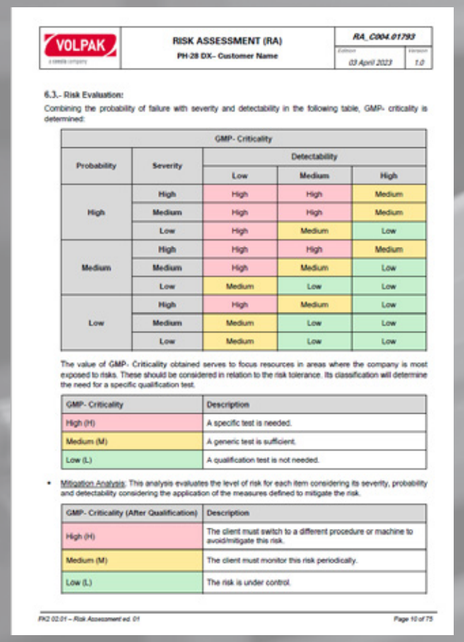

VOLPAK — RISK ASSESSMENT (RA) — PH-28 DX- Customer Name — RA_C004.01793 — Edition 03 April 2023 — Version 1.0

6.3.- Risk Evaluation:

Combining the probability of failure with severity and detectability in the following table, GMP- criticality is determined:

Probability	Severity	GMP- Criticality: Detectability: Low	Medium	High
High	High	High	High	Medium
	Medium	High	High	Medium
	Low	High	Medium	Low
Medium	High	High	High	Medium
	Medium	High	Medium	Low
	Low	Medium	Low	Low
Low	High	High	Medium	Low
	Medium	Medium	Low	Low
	Low	Medium	Low	Low

The value of GMP- Criticality obtained serves to focus resources in areas where the company is most exposed to risks. These should be considered in relation to the risk tolerance. Its classification will determine the need for a specific qualification test.

GMP- Criticality	Description
High (H)	A specific test is needed.
Medium (M)	A generic test is sufficient.
Low (L)	A qualification test is not needed.

- Mitigation Analysis: This analysis evaluates the level of risk for each item considering its severity, probability and detectability considering the application of the measures defined to mitigate the risk.

GMP- Criticality (After Qualification)	Description
High (H)	The client must switch to a different procedure or machine to avoid/mitigate this risk.
Medium (M)	The client must monitor this risk periodically.
Low (L)	The risk is under control.

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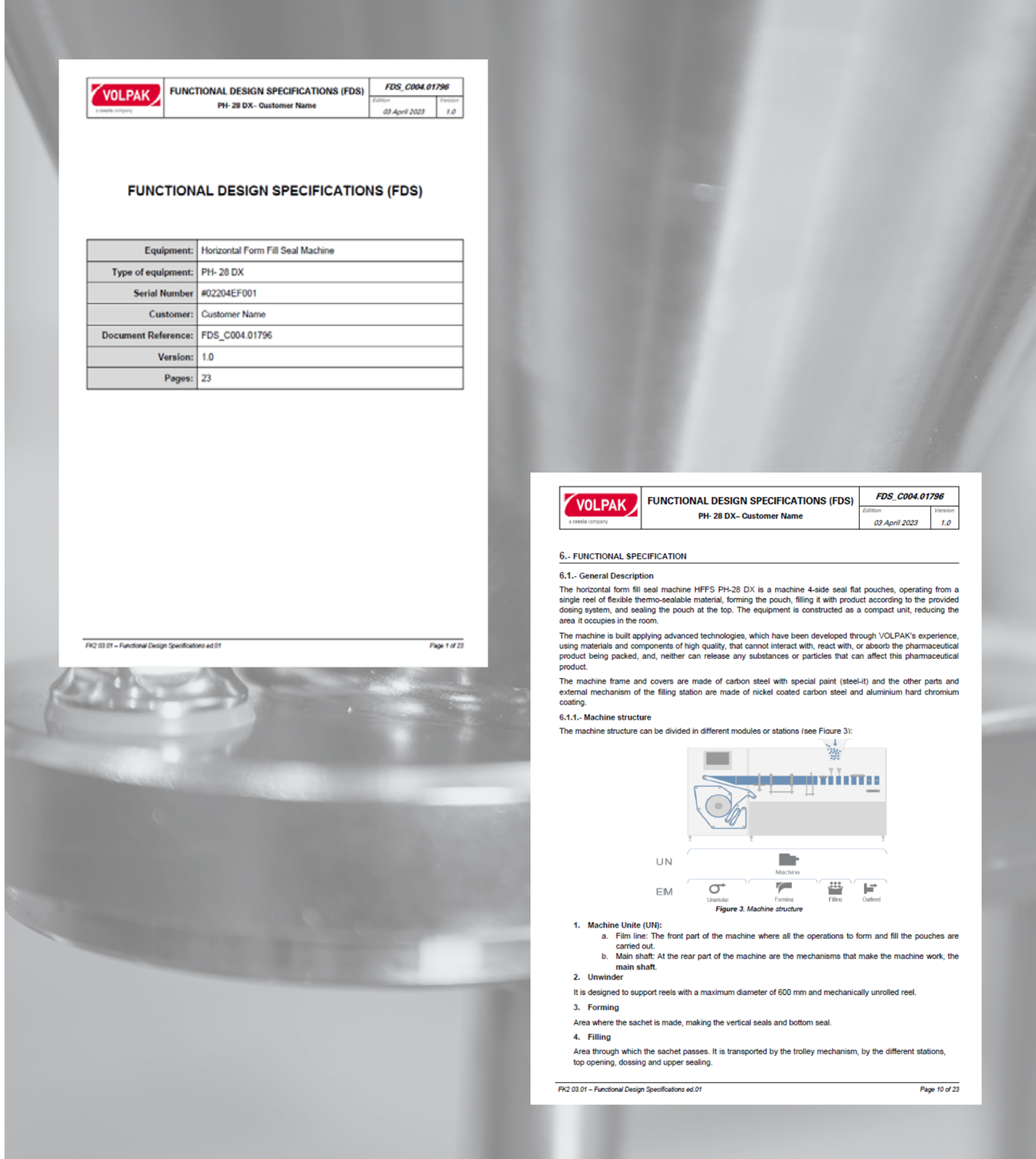
Functional and Design Specifications (FDS)

This document is prepared during the design phase and approved by the customer once the phase has been completed.

The FDS are set forth in two documents:

- FS: Functional Specifications –This document describes the functional design of the equipment.
- DS: Design Specifications –This document describes the mechanical, electric and programming design of the equipment.

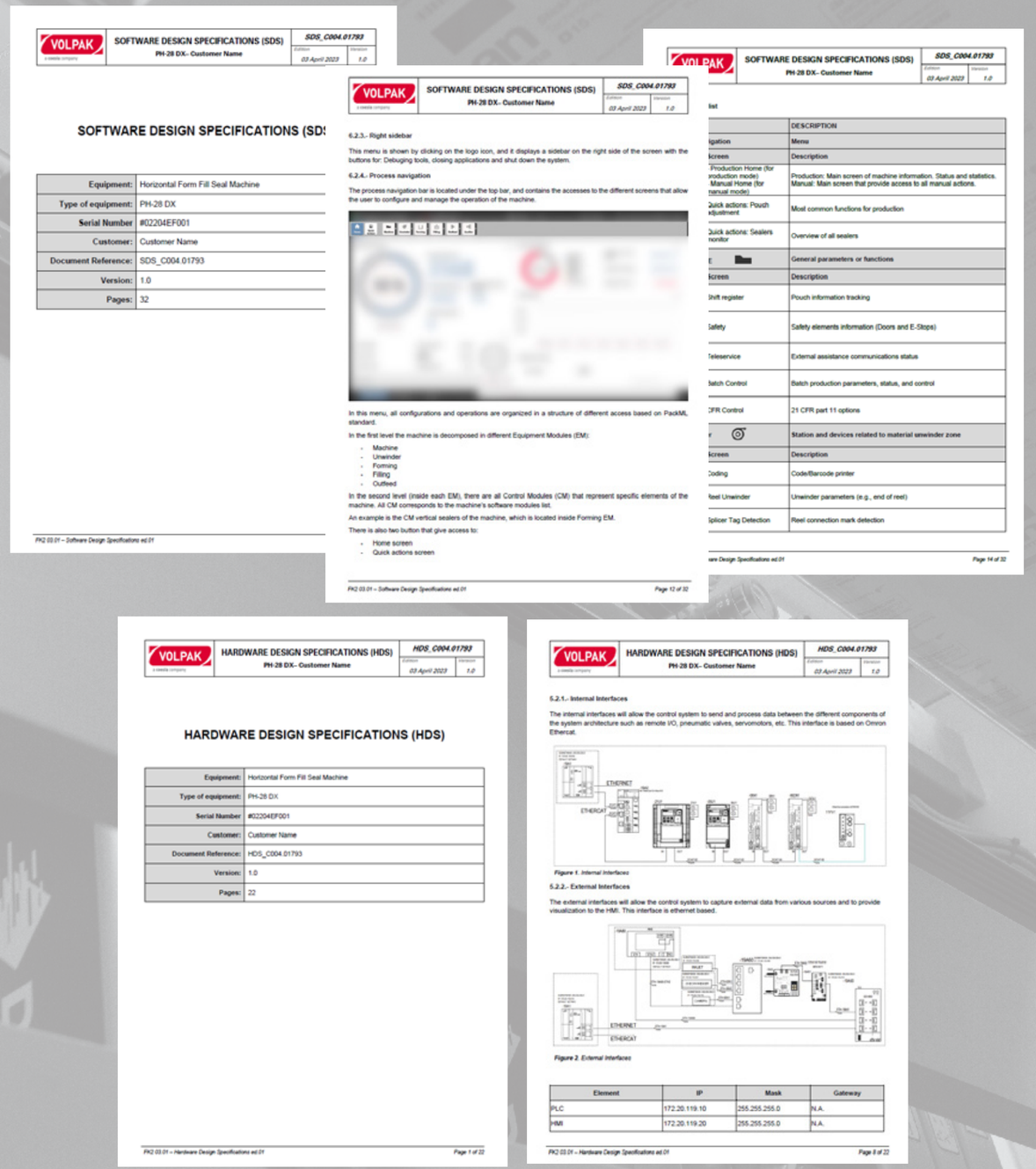


Hardware Design Specifications (HDS) & Software Design Specifications (SDS)

The HDS and SDS are the documents that detail the design of the equipment's computer and control system.

These documents serve to complement the FDS by including specific details of automation design, such as:

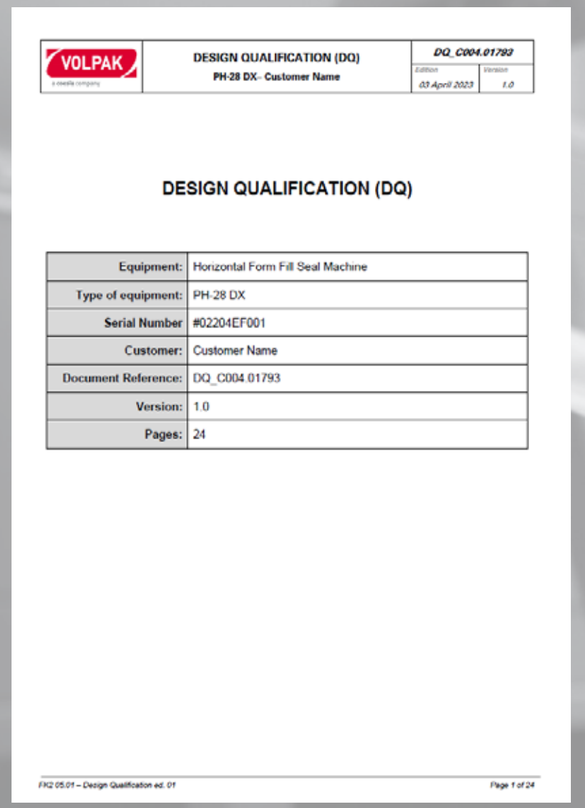
- Arquitecture
- User interface (HMI, SCADA, pushbuttons, printers)
- PLC
- Inputs and outputs
- Sensors and instruments
- Safety devices
- Power supply systems
- Communications (network)
- Operation, shut down and emergency modes
- Servomotor controls
- Alarms
- Access levels
- Critical parameters and configurable parameters (setpoints)
- Electronic records and Audit Trail



Design Qualification (DQ) Protocol

The purpose of DQ is to verify that the points described in the design documentation (FDS, SDS, HDS) comply with the requirements set out in the URS and/or offer.

DQ execution and conformity mark the starting point for equipment construction.



VOLPAK a cosela company | DESIGN QUALIFICATION (DQ) PH-28 DX- Customer Name | DQ_C004.01793 | Edition 03 April 2023 | Version 1.0

DESIGN QUALIFICATION (DQ)

Equipment:	Horizontal Form Fill Seal Machine
Type of equipment:	PH-28 DX
Serial Number	#02204EF001
Customer:	Customer Name
Document Reference:	DQ_C004.01793
Version:	1.0
Pages:	24

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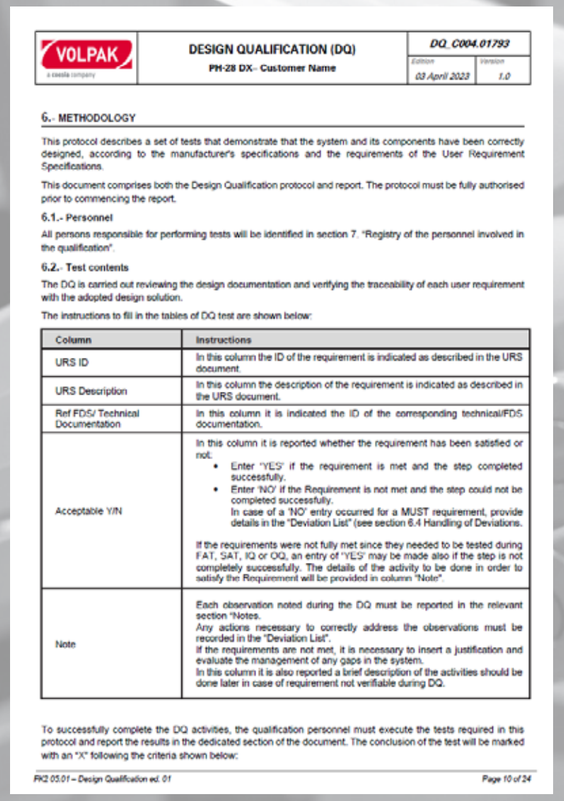

VOLPAK a cosela company | DESIGN QUALIFICATION (DQ) PH-28 DX- Customer Name | DQ_C004.01793 | Edition 03 April 2023 | Version 1.0

6.- METHODOLOGY

This protocol describes a set of tests that demonstrate that the system and its components have been correctly designed, according to the manufacturer's specifications and the requirements of the User Requirement Specifications.

This document comprises both the Design Qualification protocol and report. The protocol must be fully authorised prior to commencing the report.

6.1.- Personnel

All persons responsible for performing tests will be identified in section 7. "Registry of the personnel involved in the qualification".

6.2.- Test contents

The DQ is carried out reviewing the design documentation and verifying the traceability of each user requirement with the adopted design solution.

The instructions to fill in the tables of DQ test are shown below:

Column	Instructions
URS ID	In this column the ID of the requirement is indicated as described in the URS document
URS Description	In this column the description of the requirement is indicated as described in the URS document.
Ref FDS/ Technical Documentation	In this column it is indicated the ID of the corresponding technical/FDS documentation.
Acceptable Y/N	In this column it is reported whether the requirement has been satisfied or not. • Enter 'YES' if the requirement is met and the step completed successfully. • Enter 'NO' if the Requirement is not met and the step could not be completed successfully. In case of a 'NO' entry occurred for a MUST requirement, provide details in the "Deviation List" (see section 6.4 Handling of Deviations. If the requirements were not fully met since they needed to be tested during FAT, SAT, IQ or OQ, an entry of 'YES' may be made also if the step is not completely successfully. The details of the activity to be done in order to satisfy the Requirement will be provided in column "Note".
Note	Each observation noted during the DQ must be reported in the relevant section "Notes. Any actions necessary to correctly address the observations must be recorded in the "Deviation List". If the requirements are not met, it is necessary to insert a justification and evaluate the management of any gaps in the system. In this column it is also reported a brief description of the activities should be done later in case of requirement not verifiable during DQ.

To successfully complete the DQ activities, the qualification personnel must execute the tests required in this protocol and report the results in the dedicated section of the document. The conclusion of the test will be marked with an "X" following the criteria shown below:

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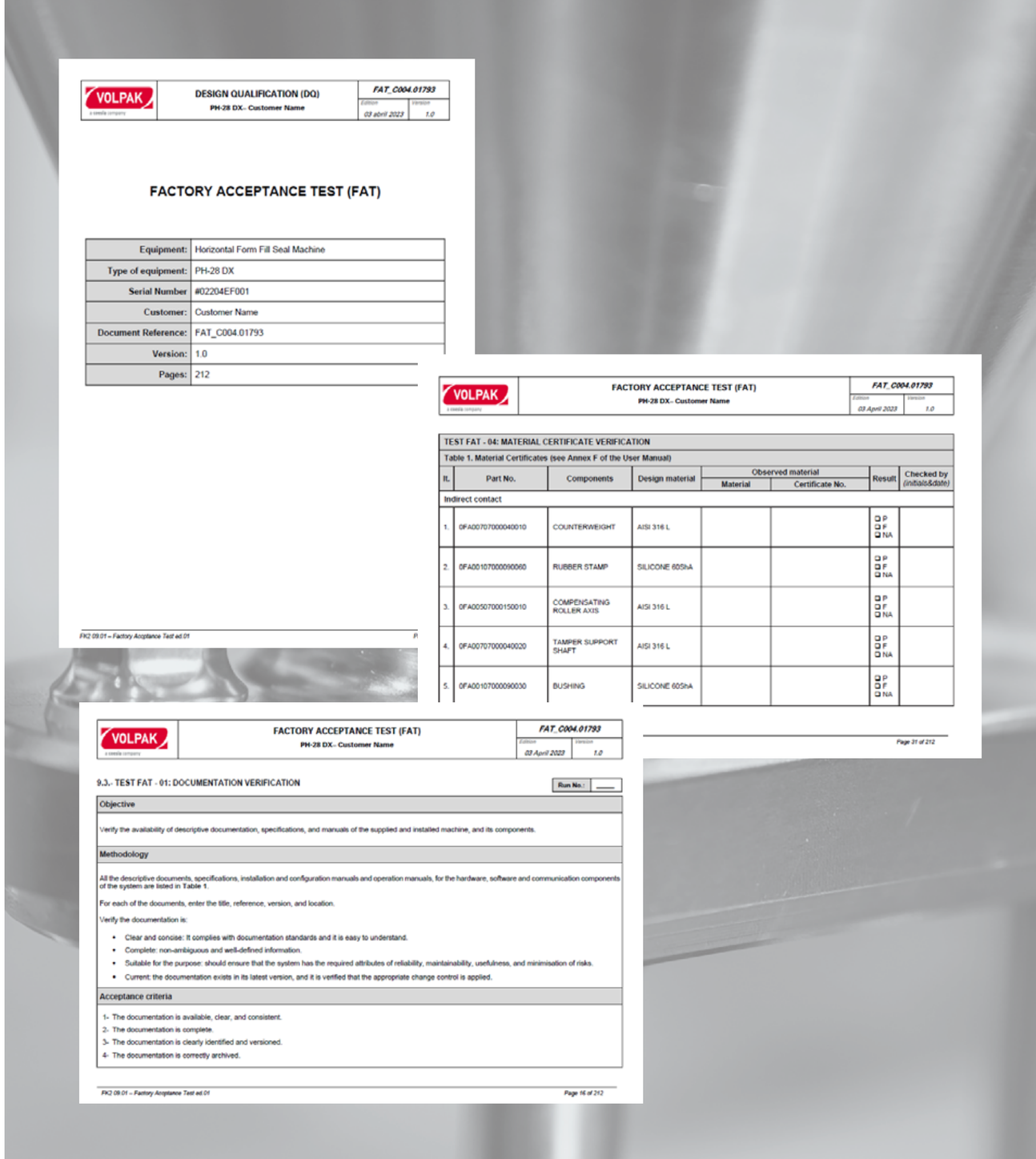
Pharma Factory Acceptance Test (FAT) Protocol

The purpose of the Pharma FAT protocol is to verify that the machine has been installed and is operating according to the customer's requirements (URS) and/or the design parameters set out in the offer or order. These verifications are carried out in the Volpak plant with the aim of accepting the equipment before it is delivered to the customer's facilities. The documentation includes an explanatory summary of each significant part of the machine and highlighting its function within the machine as a whole.

The following tests are included in the FAT protocol:

- Document verification (Draft version)
- Conformity of the plans (Draft version)
- Conformity of the components
- Verification of the parts in contact with the product (the material certificates of the components that are in contact with the product are delivered with the machine)
- Verification of calibration process instruments (the calibration certificates of the temperature probes supplied with the machine are delivered with the machine)
- Verification of Installation and Software Version of the HMI and PLC
- I/O Verification
- Start-up, shut down and communication failures
- Screens verification
- Access levels test (if required)
- Verification of safety systems
- Alarms and interlocks
- Parameter management
- Audit trail verification (if required)
- Data backup and retrieval (if required)
- Rejections
- Operation test for each format
- Dosing capacity/precision
- Verification of report generation (if required)



SAT (Site Acceptance Test) Protocol

The purpose of the SAT protocol is to provide documentary evidence that the equipment has been delivered, installed and operates in compliance with its design specifications.

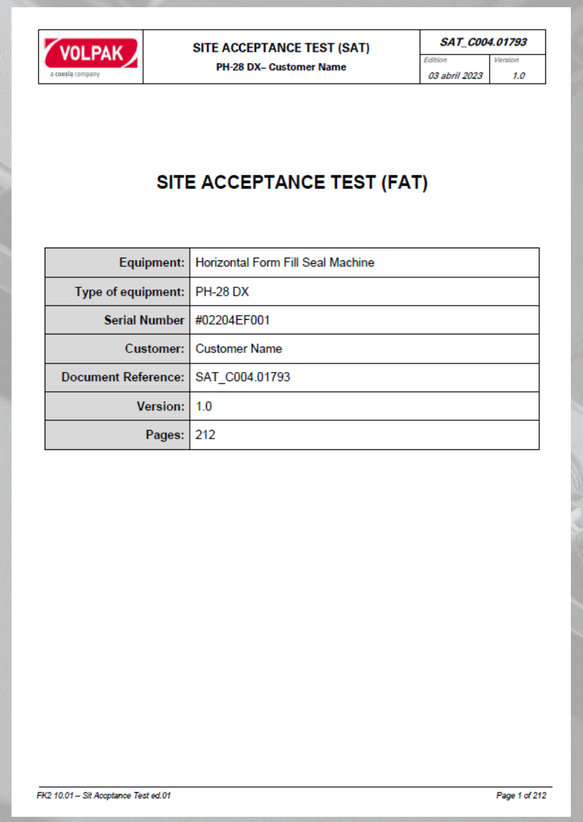
The following tests are included in the SAT protocol:

- Document verification (Final version)
- Operation test for each format
- Dosing capacity/precision

Each FAT and SAT test must include the following:

- Purpose of the test;
- Methodology for test performance;
- Acceptance criteria: minimum parameter values required to accept the test;
- Comments section to describe failures deviations or enter observations;
- Checkbox for the signature of the person responsible for performing the test;
- Approval checkbox to be signed when the test is accepted.

When the verifications performed during the Pharma FAT and SAT tests are satisfactory, properly documented and not affected by machine transport or any changes made to the machine, they can be referenced in subsequent qualification stages without having to repeat the tests.



VOLPAK a coesia company | SITE ACCEPTANCE TEST (SAT) PH-28 DX– Customer Name | SAT_C004.01793 | Edition: 03 abril 2023 | Version: 1.0

SITE ACCEPTANCE TEST (FAT)

Equipment:	Horizontal Form Fill Seal Machine
Type of equipment:	PH-28 DX
Serial Number	#02204EF001
Customer:	Customer Name
Document Reference:	SAT_C004.01793
Version:	1.0
Pages:	212

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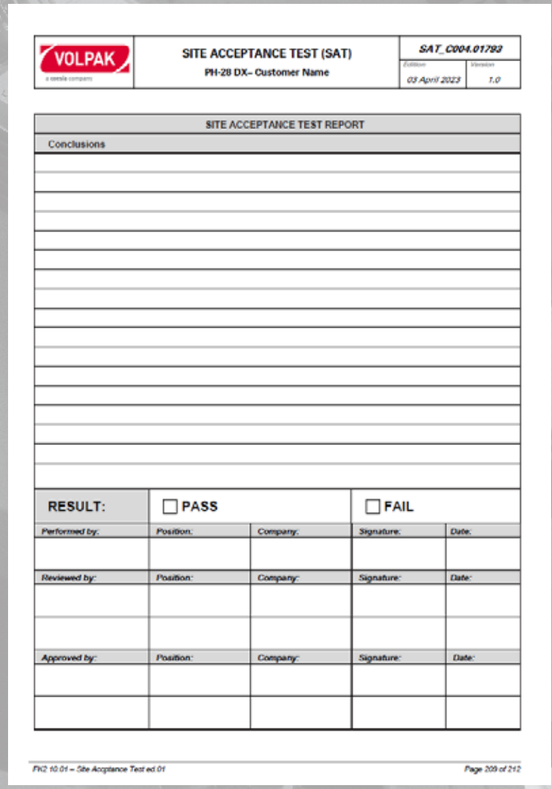


VOLPAK a coesia company | SITE ACCEPTANCE TEST (SAT) PH-28 DX– Customer Name | SAT_C004.01793 | Edition: 03 April 2023 | Version: 1.0

SITE ACCEPTANCE TEST REPORT

Conclusions

RESULT:	☐ PASS		☐ FAIL	
Performed by:	Position:	Company:	Signature:	Date:
Reviewed by:	Position:	Company:	Signature:	Date:
Approved by:	Position:	Company:	Signature:	Date:

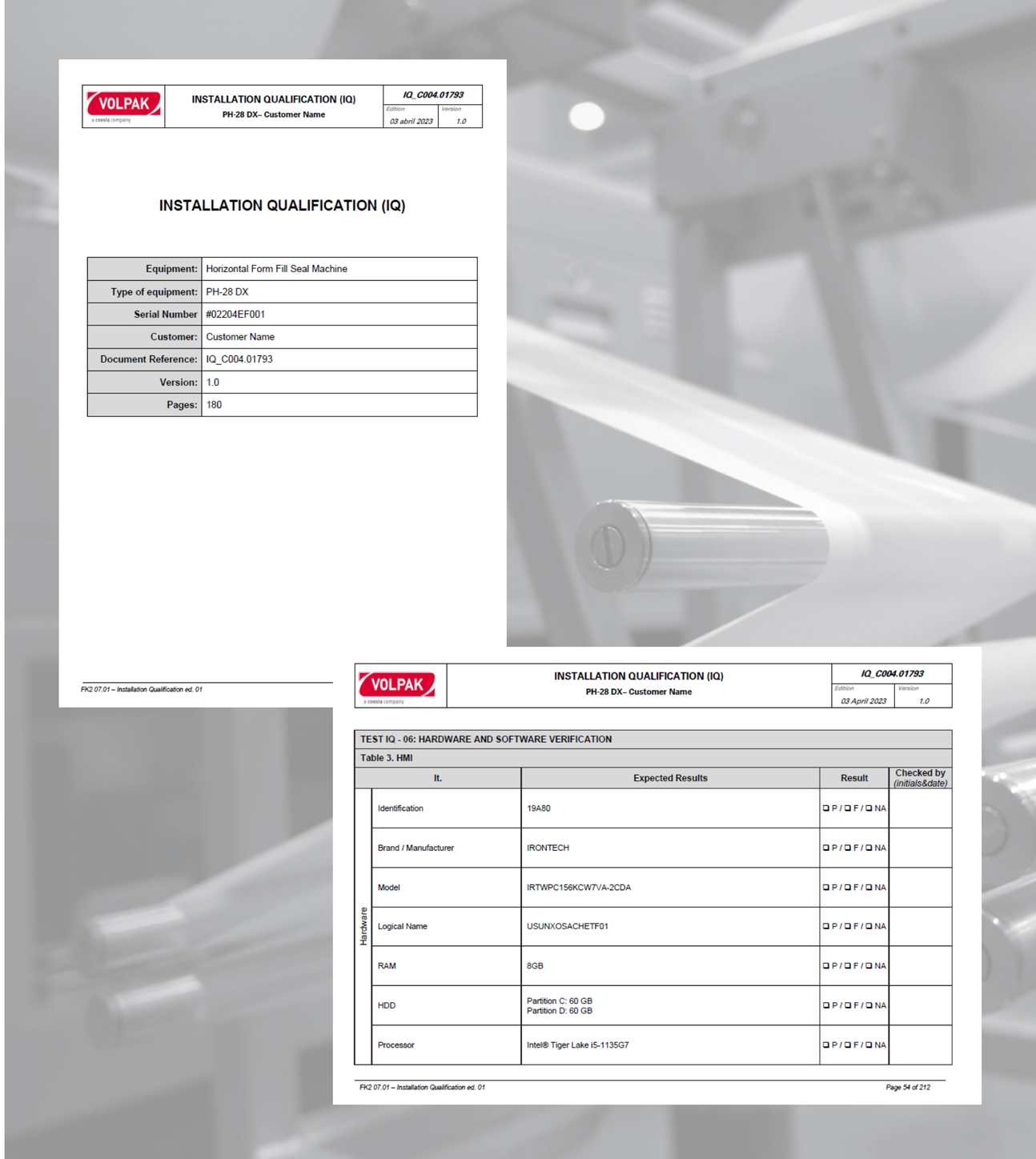
FK2 10.01 – Site Acceptance Test ed.01 — Page 209 of 212

IQ (Installation Qualification) Protocol

The purpose of the IQ protocol is to verify that the machine has been installed according to the customer's requirements (URS) and/or the design parameters set out in the offer or order. These checks are carried out without starting up the machine. The documentation includes an explanatory summary of each significant part of the machine and highlighting its function within the machine as a whole.

The following tests are included in the IQ protocol:

- Preliminary verification (FAT Approval)
- Document verification (Final version)
- Conformity of the plans (Final version)
- Conformity of the components
- Verification of the parts in contact with the product (the material certificates of the components that are in contact with the product are delivered with the machine)
- Verification of calibration process instruments (the calibration certificates of the temperature probes supplied with the machine are delivered with the machine)
- Verification of Installation and Software Version of the HMI and PLC
- I/O Verification
- Verification of services (equipment supplies and connections)



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INSTALLATION QUALIFICATION (IQ) PH-28 DX– Customer Name	IQ_C004.01793 Edition: 03 abril 2023 — Version: 1.0

INSTALLATION QUALIFICATION (IQ)

Equipment:	Horizontal Form Fill Seal Machine
Type of equipment:	PH-28 DX
Serial Number	#02204EF001
Customer:	Customer Name
Document Reference:	IQ_C004.01793
Version:	1.0
Pages:	180

FK2 07.01 – Installation Qualification ed. 01

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INSTALLATION QUALIFICATION (IQ) PH-28 DX– Customer Name	IQ_C004.01793 Edition: 03 April 2023 — Version: 1.0

TEST IQ - 06: HARDWARE AND SOFTWARE VERIFICATION

Table 3. HMI

	It.	Expected Results	Result	Checked by *(initials&date)*
Hardware	Identification	19A80	❑ P / ❑ F / ❑ NA	
	Brand / Manufacturer	IRONTECH	❑ P / ❑ F / ❑ NA	
	Model	IRTWPC156KCW7VA-2CDA	❑ P / ❑ F / ❑ NA	
	Logical Name	USUNXOSACHETF01	❑ P / ❑ F / ❑ NA	
	RAM	8GB	❑ P / ❑ F / ❑ NA	
	HDD	Partition C: 60 GB Partition D: 60 GB	❑ P / ❑ F / ❑ NA	
	Processor	Intel® Tiger Lake i5-1135G7	❑ P / ❑ F / ❑ NA	

FK2 07.01 – Installation Qualification ed. 01 — *Page 54 of 212*

OQ (Operational Qualification) Protocol

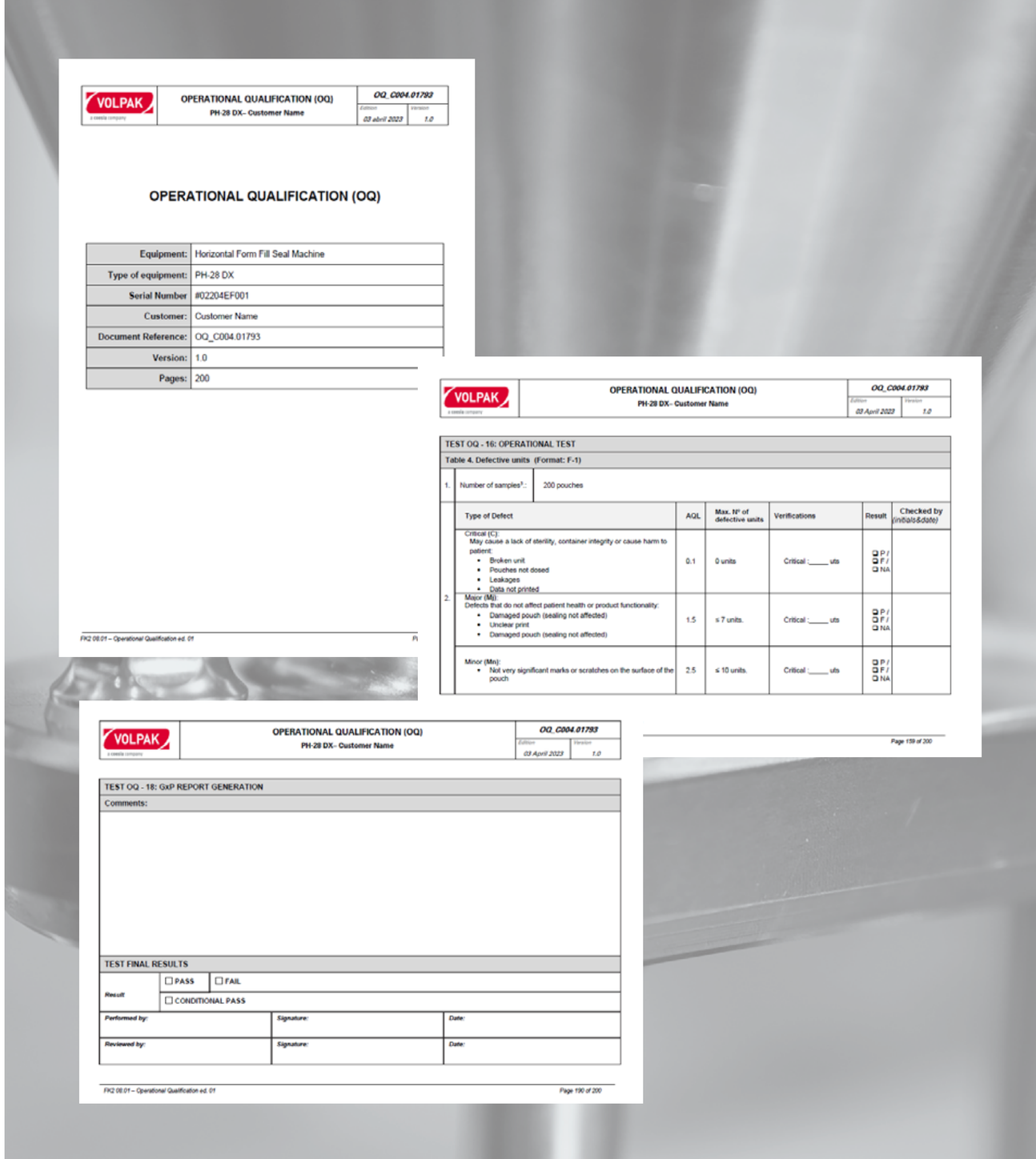
The purpose of this protocol is to verify that the machine operates according to the customer's requirements (URS) and/or the design parameters set out in the offer or order. The documentation includes an explanatory summary of each significant part of the machine and highlighting its function within the machine as a whole.

The following tests are included in the OQ protocol:

- Preliminary verification
- Start-up, shut down and communication failures
- Screens verification
- Access levels test (if required)
- Verification of Safety Systems
- Alarms and interlocks
- Parameter Management
- Audit Trail Verification (if required)
- Data backup and retrieval (if required)
- Rejections
- Operation test for each format
- Dosing capacity/precision
- Verification of report generation (if required)

Each IQ and OQ test must include the following:

- Purpose of the test;
- Methodology for test performance;
- Acceptance criteria: minimum parameter values required to accept the test;
- Comments section to describe failures deviations or enter observations;
- Checkbox for the signature of the person responsible for performing the test;
- Approval checkbox to be signed when the test is accepted.



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