Content

1. Validation Protocol

IKA Article Number	
IKA Quotation Number	
PO Number	
Service order Number	
IKA Contact	Name, Place and Date
Customer Contact	Name, Place and Date

1.1. Comment

1.2. IQ Acceptance criteria

IQ Test(s)	Acceptance criterial fulfilled	
	☐ Yes	☐ No
	☐ Yes	☐ No
	☐ Yes	☐ No
	☐ Yes	☐ No
	☐ Yes	☐ No
	☐ Yes	☐ No
Test result		
Acceptance criteria / criteria met? (see deviation report no .:)	☐ Yes	☐ No

	Date	Name	Signature
Test executed			
Test validated			

1.3. OQ Acceptance criteria

OQ Test(s)	Acceptance criteria fulfilled	
	☐ Yes	☐ No
	☐ Yes	☐ No
	☐ Yes	☐ No
	☐ Yes	☐ No
	☐ Yes	☐ No
	☐ Yes	☐ No
Test result		
Acceptance criteria / criteria met? (see deviation report no .:)	☐ Yes	☐ No

	Date	Name	Signature
Test executed			
Test validated			

1.4. PQ Acceptance criteria

PQ Test(s)	Acceptance criteria fulfilled	
	☐ Yes	☐ No
	☐ Yes	☐ No
	☐ Yes	☐ No
	☐ Yes	☐ No
	☐ Yes	☐ No
Test result		
Acceptance criteria / criteria met? (see deviation report no .:)	☐ Yes	☐ No

	Date	**Name**	**Signature**
Test executed			
Test validated			

2. Release of the validation protocol

The following tests were performed.		
Deviations were found:	☐ Yes	☐ No
See deviation report (s):		
The signatures confirm that all tests have been carried out accordingly and deviations have been documented accordingly.		

Executed tests	Date	Name	Signature
See IQ			
See OQ			
See PQ			

3. Overview of the detected deviations of the validation

This page can be copied if more than 15 deviations have been detected! In this case, the page numbers must be filled out by hand. Side of

No.	Test No.	Deviation	Classification	Deviation corrected?	Date / Signature
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					

Deviation classification:
Critical: Fatal error that makes further processing of the protocol impossible until the deviation is eliminated
Serious: Error that allows the further processing of the protocol, but prevents the execution of the next qualification phase to error correction.
Low: Error that neither affects the product nor endangers the operators. Further processing of the qualification protocols will not be hindered.

4. Deviation Report

Copy this page only in case of multiple deviations!							
Determined deviation No .:							
Test No.: –		Page:		Product:		Version:	
Description:							
Classification:	☐ critical		☐ serious		☐ low		
Deviation detected by:							
Date:		Name:		Signature:			
Necessary measures:							
Approved by:							
Date:		Name:		Signature			
Result of the action (s):							
Acceptance criteria / criteria met? (see deviation report no .:)					☐ Yes	☐ No	

	Date	Name	Signature
Test repeated			
Test checked			

Content

1. Validation scope

Description of the product
Description of the validation (URS – User Requirement Specification)
Time schedule / Planned time schedule for the validation

2. Release of the validation plan

	Job Title	Name	Signature
IKA Quotation Number			
Author:			
Checked:			
Release:			
Release:			

3. List of Abbreviations

Abbreviation	Description
DQ	During design qualification, all components, assemblies, system parts, filters and controls are documented in order to prove that they correspond to the intended design and are suitable for the intended purpose. IKA supports you in this by confirming the requirements / functional specifications or your URS (User Requirement Specification), providing technical data or through feasibility studies in our application laboratory. Depending on the work involved, costs may be incurred that will be reimbursed to you in the event of a device purchase.
IQ	Installation qualification is documented proof that the equipment, systems and components in the installed or modified version meet the previously defined requirements. IKA supports you in this qualification step by providing the certificates and documents that confirm the identification and proper functioning and delivery of our devices. You will receive ready-made documents / checklists for the specific product, which you can check point by point on site. If required, IKA will perform the qualification step for you on site and check the installation conditions in your laboratory.
OQ	During operation qualification, the functions of the system or the equipment are checked for compliance with the requirements. IKA supports you in this step with clear instructions for carrying out relevant functional tests and makes recommendations for suitable measuring equipment, if necessary according to the respective standard to be complied with. If required, IKA will carry out the qualification step for you on site. At the same time, IKA will provide you with important information on the qualification of your employees in order to avoid operating errors on the device.
PQ	Performance qualification demonstrates that the premises and infrastructure systems, in combination with the production equipment, are suitable for manufacturing products of the agreed quality in a reproducible manner. IKA will be happy to support you in putting your system into operation. IKA mainly assesses the proper functioning of the devices in operation and helps to adjust parameters if necessary. The quality of the respective device is usually assessed by our customer. If required, IKA will support you on site with performance qualification.

4. System Requirements

5. Technical Data

6. System Description

IKA Article Number	Description

7. Scope of Delivery

Name

8. Training

The training will be conducted at the customer side by IKA service or by a qualified distributor. The sign off of the training will be done at this validation protocol.

9. Principles for the implementation of validation

9.1. General

9.1.1. Purpose of the documentation

This document describes the activities for validation.

9.1.2. Place of Validation

The tests described in this document are to be done at the customer.

9.1.3. Necessary knowledge

To perform the tests described in this document, the testers must have the following knowledge and rights:

- Necessary rights to release and publish the IQ/OQ/PQ
- Knowledge of the function of the product and metrology equipment if applicable
- General product and customer specific safety rules

9.1.4. Behavior in case of deviations

Any discrepancies found during the processing of the tests of this document must be documented correctly.
All detected deviations must be included in:

- the "overview of identified deviations"
- the form "deviation report"

The form "deviation report" describes in each case a deviation (and possibly necessary corrective measures) in detail.

Specifically, the following information must be entered in this form:

- Test no. / Page number of the test sheet / machine / version
- Description of deviation
- Deviation classification
- Name, date, signature of the tester
- Measures to eliminate the deviation
- Result of the measures for elimination
- Possible (negative) effects of the remedial measures

9.2. Documentation of the test results

9.3. General regulations

9.3.1. Documentation release

The test is carried out on the basis of test sheets, which together with other forms produce this document.
The entries under "Document Created" are made by the author of this document.
A specialist of the department then checks the test sheets for factual accuracy, completeness and feasibility of the tests and documents his activity under 'Documentation Checked'.
After a representative of the operating company has released the document (documentation released for the application), the tests can begin.

9.4. Test sheets

The tests are performed by one or two testers. The test results are to be documented in the corresponding test sheets. In this case, the tester or testers must indicate the date of implementation and sign the test.

9.4.1. Other documents

If additional documents are used for the test procedure (lists, etc.), these documents must be included in Chapter 5 (Appendix) and entered in the overview list.

9.4.2. Qualification report

After all the tests have been completed, the 'Qualification Report' form will be completed and signed by the tester (s). A representative of the operating company formally checks that all tests have been carried out and documented properly and signs the document under tests.

9.4.3. Incorrect entries on test log

When correcting write and transfer errors, note that corrections that make the original erroneous entry illegible are not allowed. When correcting, the erroneous entry must be crossed out so that it remains readable. The correct entry should be written next to the crossed-out incorrect entry. In addition, the correction must be signed with an indication of the date and the reason for the correction.

9.4.4. Not filled in form fields

In form fields that are not filled in, the note "N.A." (= not applicable) must be entered.

10. **Validation plan**

The following validation tests to be performed:

IQ: INSTALLATION QUALIFICATION

OQ: OPERATION QUALIFICATION

PQ: PERFORMANCE QUALIFICATION