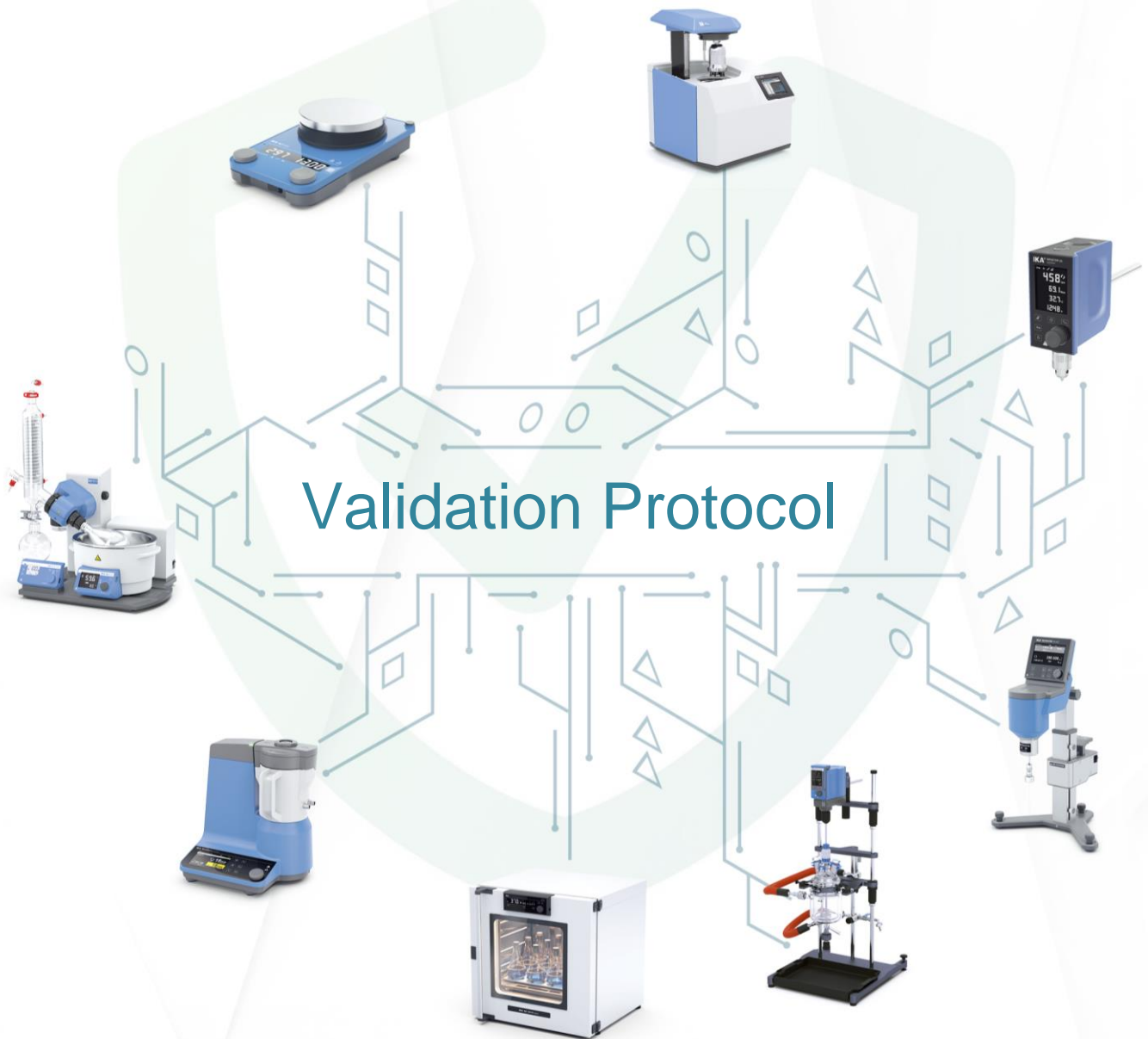


IKA

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IKA device





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IQ/OQ Protocol

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IQ/OQ Protocol

1. Validation Protocol

IKA article number	
IKA product description	
IKA Order number	
Customer PO number	
IKA contact	
Customer contact	

1.1. Comment

1.2. Scope of delivery

IKA article number	Product description

IQ/OQ Protocol

1.3. IQ Acceptance criteria

IQ Test(s)	Acceptance criterial fulfilled	
Requirements for a correct installation have been checked (voltage, Place of installation, Mediums e.g. O ₂ ; exhaust air, etc.) and are OK?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Visual inspection - no damages?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
...	<input type="checkbox"/> Yes	<input type="checkbox"/> No
...	<input type="checkbox"/> Yes	<input type="checkbox"/> No
...	<input type="checkbox"/> Yes	<input type="checkbox"/> No
...	<input type="checkbox"/> Yes	<input type="checkbox"/> No
...	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Test result

Acceptance criteria / criteria met? (see deviation report no. :)		<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Date	Name	Signature
Test executed			
Test validated			



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1.4. OQ Acceptance criteria

OQ Test(s)	Acceptance criteria fulfilled	
Product Training / Introduction: (Content of Operating Instruction) done and OK <ul style="list-style-type: none">• Safety Relevant Topics according Manual• Intended use• Introducing the operation features	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Device is OK after start (all LED segments light up during the self-test; no error codes appear)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
...	<input type="checkbox"/> Yes	<input type="checkbox"/> No
...	<input type="checkbox"/> Yes	<input type="checkbox"/> No
...	<input type="checkbox"/> Yes	<input type="checkbox"/> No
...	<input type="checkbox"/> Yes	<input type="checkbox"/> No
...	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Test result

Acceptance criteria / criteria met? (see deviation report no.:)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
--	------------------------------	-----------------------------

	Date	Name	Signature
Test executed			
Test validated			



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2. Release of the validation protocol

The following tests were performed.

See validation protocol

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			

IQ/OQ Protocol

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.



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IQ/OQ Protocol

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 executed			
Test validated			