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Title of IQ

Reason for this IQ

new equipment
 Modification / repair
 Re-Location
 Others:

Approvals:

IQ Plan: Signature documents the approval of IQ Plan

	Name	Signature	Date
Author			
Production			
QA/RA			

IQ Report: Signature documents the review of results and the approval of IQ Report

	Name	Signature	Date
Author			
Production			
QA/RA			

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2. Activities of IQ

This section must be completed prior to approval of IQ Report.

2.1 Description of equipment

Description of activities: Verify if manufacturer and type is correct. Document the serial number. Verify if equipment is CE-marked.

Acceptance Criteria	Evaluation	
1. Manufacturer:	yes <input type="checkbox"/>	no <input type="checkbox"/>
2. Type:	<input type="checkbox"/>	<input type="checkbox"/>
3. Serial number:	n/a	
4. CE-mark	<input type="checkbox"/>	<input type="checkbox"/>

Attachments:

Results: <input type="checkbox"/> accepted <input type="checkbox"/> Not accepted (describe actions needed below)

Remarks / actions needed:

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2.2 Manuals from supplier

Description of activities:
Verify if all manuals from the manufacturer/supplier are available and document the storage area.

Acceptance Criteria	Evaluation	
	Yes	No
1. Manuals from supplier are available Storage:	<input type="checkbox"/>	<input type="checkbox"/>

Attachments:

Results: accepted Not accepted (describe actions needed below)

Remarks / actions needed:

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2.3 Procedures and training

Description of activities:
 Verify if all procedures (like work instructions, control plans, ...) are available and trained.

Acceptance Criteria	Evaluation	
	yes	no
1. xxx is available and trained.	<input type="checkbox"/>	<input type="checkbox"/>
2. xxx is available and trained.	<input type="checkbox"/>	<input type="checkbox"/>
3. xxx is available and trained.	<input type="checkbox"/>	<input type="checkbox"/>
4. xxx is available and trained.	<input type="checkbox"/>	<input type="checkbox"/>

Attachments:
 Training records

Results: accepted Not accepted (describe actions needed below)

Remarks / actions needed:

Executed by _____ Date _____ Signature _____

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2.4 Accessories, tools and components

Description of activities:

Verify if all accessories, tools and components were delivered and/or added to the work station as needed.

Acceptance Criteria	Evaluation	
	yes	no
1. all accessories, tools and components were delivered and/or added to the work station, see attachments	<input type="checkbox"/>	<input type="checkbox"/>
2.	<input type="checkbox"/>	<input type="checkbox"/>

Attachments:

List of accessories, tools and components

Results:

accepted

Not accepted (describe actions needed below)

Remarks / actions needed:

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2.5 Supply systems and interfaces

Description of activities:
Verify that all supplies needed are available and that the equipment was installed correctly.

Acceptance Criteria	Evaluation	
	yes	No
1. Equipment was connected to electrical power supply: xxV/xxHz	<input type="checkbox"/>	<input type="checkbox"/>
2. Equipment was connected to compressed air system \geq xx bar	<input type="checkbox"/>	<input type="checkbox"/>

Attachments:

Results: accepted Not accepted (describe actions needed below)

Remarks / actions needed:

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2.6 Maintenance and cleaning

<p>Description of activities: Verify that requirements for maintenance were determined. Verify that requirements for cleaning were determined. Reference the relevant documents.</p>
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Acceptance Criteria	Evaluation	
	yes	No
1. Maintenance instructions are defined, see xxx.	<input type="checkbox"/>	<input type="checkbox"/>
2. Cleaning instructions are defined, see xxx.	<input type="checkbox"/>	<input type="checkbox"/>

Attachments:

Results: <input type="checkbox"/> accepted <input type="checkbox"/> Not accepted (describe actions needed below)

Remarks / actions needed:

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2.7 Drawings and spare parts

Not required, see section 2

<p>Description of activities: Verify that all drawings are collected and listed. Verify that the need for spare parts was determined.</p>
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Acceptance Criteria	Evaluation	
	Ja	Nein
1. Drawings are collected and listed, see attachments	<input type="checkbox"/>	<input type="checkbox"/>
2. Spare parts and listed, see attachments	<input type="checkbox"/>	<input type="checkbox"/>

<p>Attachments: List of drawings and spare parts</p>
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<p>Results: <input type="checkbox"/> accepted <input type="checkbox"/> Not accepted (describe actions needed below)</p>
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<p>Remarks / actions needed:</p>

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2.8 Instruments and calibration

Description of activities:
 Verify that all instruments are present and calibrated.
 Verify that calibration labels were added and calibration dates are valid.

Acceptance Criteria	Evaluation	
	Ja	Nein
1. Instruments are present and calibrated.	<input type="checkbox"/>	<input type="checkbox"/>
2. Calibration labels were added and calibration dates are valid.	<input type="checkbox"/>	<input type="checkbox"/>

Attachments:
 List of all instruments, evidence of labeling with calibration stickers

Results: accepted Not accepted (describe actions needed below)

Remarks / actions needed:

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2.9 Alarms and controls

<p>Description of activities: Verify that all alarms and controls are present. Perform test on all alarms and controls.</p>
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Acceptance Criteria	Evaluation	
	yes	No
1. Alarms and controls are present, see attachment	<input type="checkbox"/>	<input type="checkbox"/>
2. The correct functioning of alarms and controls were tested, see attachments	<input type="checkbox"/>	<input type="checkbox"/>

<p>Attachments: List of alarms and controls</p>

<p>Results: <input type="checkbox"/> accepted <input type="checkbox"/> Not accepted (describe actions needed below)</p>
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<p>Remarks / actions needed:</p>

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2.10 Environmental conditions

Description of activities:
 Verify if the supplier/manufacturer of the equipment specified environmental conditions (like temperatures, humidity, vibration, location ...) and if those conditions are adhered to.

Acceptance Criteria	Evaluation	
	yes	No
1. Conditions are specified as	<input type="checkbox"/>	<input type="checkbox"/>
2. Conditions are adhered to	<input type="checkbox"/>	<input type="checkbox"/>

Attachments:

Results: accepted Not accepted (describe actions needed below)

Remarks / actions needed:

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2.11 Software

Description of activities:
Identify the hardware and software installed and their intended use. Verify if backup/reload was planned and/or completed.

Hardware:

Activities	Results / Documentation		
1. Verify if the following software is installed:	yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	Remarks:		
2. is reloading / backup planned / completed?	yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
Location of software backup:	Remarks:		
3. Intended use of software:			
4. Is an additional software validation needed?	yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	Justification:		

Attachments:

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Results:	<input type="checkbox"/> accepted	<input type="checkbox"/> Not accepted (describe actions needed below)
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<p>Remarks / actions needed: If additional software validation is needed, describe were this was done / will be done.</p>

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2.12 Functional testing

Description of activities: Verify, if equipment works correctly

Acceptance Criteria	Evaluation	
	Ja	Nein
1. Equipment works correctly and a test run was conducted as per	<input type="checkbox"/>	<input type="checkbox"/>
2. Further testing includes.....	<input type="checkbox"/>	<input type="checkbox"/>

Attachments:

Results: <input type="checkbox"/> accepted <input type="checkbox"/> Not accepted (describe actions needed below)

Remarks / actions needed:

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3. Results, events and failures

This section must be completed prior to approval of IQ Report.

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4. Summary of results

This section must be completed prior to approval of IQ Report.

Activities	Results		
	passed	Not passed	n.a.
2.1 Description of equipment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Manuals from supplier	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.3 Procedures and training	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4 Accessories, tools and components	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.5 Supply system and interfaces	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.6 Maintenance and cleaning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.7 Drawings and spare parts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.8 Instruments and calibration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.9 Alarms and controls	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.10 Environmental conditions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.11 Software	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.12 Functional testing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Results are accepted, IQ is considered passed.

Results were not accepted and the following actions are required: