TITLE:	PERFORMANCE QUALIFICATION OF THE SHIPPING BOX PROTOCOL-2017				
Report Number	IOQ-SBX-xxx-xxxx-P	**Revision**	0	**Issued Date**	dd-mm-yyyy

COMPANY NAME:	**XXXXXXXXXX**
SITE	**SHIPPING BOX**
LOCATION:	**xxxxxxxxxxx**

PROTOCOL PREPARED BY		
NAME	**SIGNATURE**	**DATE**
Name: **Title:** **Company:** Vacker Global		dd-mm-yyyy
PROTOCOL APPROVED BY		
NAME	**SIGNATURE**	**DATE**
Name: **Title:** **Company:**Vacker Global		dd-mm-yyyy

PROTOCOL APPROVAL		
NAME	**SIGNATURE**	**DATE**
Name: xxxx **Title:** **Company:**		
Name: xxxx **Title:** **Company:**		
Name: xxxx **Title:** **Company:**		

CHANGE HISTORY			
NAME	**REASON FOR CHANGE**	**REVISION**	**ISSUED DATE** (dd-mm-yyyy)
	New document	0	dd-mm-yyyy

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1 IDENTIFICATION OF THE QUALIFICATION TEAM

In order to identify the persons who have participated in the execution of this qualification, a specimen of their signature and initial is shown below, beside their name and title.

Name	Title	Signature	Initial

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2 DEFINITIONS AND ACRONYMS

In order to facilitate the comprehension of terms and acronyms used in this document, a brief technical definition is shown below.

Terms	Definitions
Auxiliary Equipment	Equipment mostly used in conjunction with the equipment to be qualified but not included in the qualification package.
Change Parts	Parts to fit different size / format or application.
Component	Any major piece, part or assembly of the main equipment or sub-equipment that does not have its own power supply and could not operate as a standalone unit (valves, switches, etc.).
Controller	A device that interprets a mechanical, digital or analog signal, generated by a sensor, to control an equipment or component.
Controller, critical	A controller for which control have a direct impact on the quality of the product or proper operation of the equipment.
Controller, non-critical	A controller for which control have no direct impact on the quality of the product or proper operation of the equipment.
Deviation	For IQ: Any discrepancy between the installation specifications and the actual (as found) installation. For OQ: Any discrepancy between the protocol and the actual performed test, test function methodology, testing equipment, testing material etc.
Instrument	A device that interprets a mechanical, digital or analog signal generated by a sensor, and converts it into engineering units (°C, % RH, mA, etc.) through scaling.
Instrument, critical	An instrument for which measurements have a direct impact on the quality of the product or proper operation of the equipment.
Instrument, non-critical	An instrument for which measurements have no direct impact on the quality of the product or proper operation of the equipment.
Key Operating Parameters	Parameters that must be maintained to process or produce products with consistent quality attributes and those that may have an impact on the proper operation of the equipment.
Main Equipment	Major equipment to be qualified.
Sensor	A mechanical device (pressure switch, bimetal temperature switch, etc.), a digital or analog transducer (limit switch, pressure sensor, temperature sensor, etc.) that generates an electrical or mechanical signal to an instrument or a controller in order to be interpreted.
Sensor, critical	A sensor for which detection has a direct impact on the quality of the product or proper operation of the equipment.
Sensor, non-critical	A sensor for which detection has no direct impact on the quality of the product or proper operation of the equipment.
Sub-equipment	Piece of equipment, part of major equipment that possesses its own power supply that could usually operates as a standalone unit (pump, conveyor etc.).

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Terms	Definitions
D	Deviation
ID	Identification
IQ	Installation Qualification
IOQ	Installation / Operational Qualification
N/Ap.	Not Applicable
N/Av.	Not Available
N/Sp.	Not Specified
NIST	National Institute of Standards and Technology
OQ	Operational Qualification
PM	Preventive Maintenance
QA	Quality Assurance
QC	Quality Control
S/N	Serial number
SOP	Standard Operating Procedure

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3 SCOPE

The Performance Qualification protocol is a comprehensive document, which will be used to guide the executants, in the verification of the proper performance of the shipping box located at xxxx Warehouse.

4 OBJECTIVE

The purpose of this Performance qualification (PQ) is to:

- Verify that the configuration of the packaging method, as established according to the directive of Xxxxxx, is set up to eliminate risk of product excursion from specified temperature limit.
- Ensure that the packaging method can maintain the product within the specified temperature range when the container is exposed to external temperature variations. Specific test study is designed to verify that the packaging method preserves the product from climatic influences.

5 RATIONALE

Proper performance will be established based on the following characteristics:

- **Proper temperature control under empty conditions**
- **Power failure under empty condition.**
- **Proper temperature control under loaded conditions.**
- **Proper temperature recovery following a door opening under loaded conditions.**
- **Power failure under loaded condition.**

As the Shipping box will be used in transportation mode 12v DC and in a warehouse on AC, the qualification tests will be performed in both mode.

All tests must be conducted by trained and experienced technical personnel and must be documented in a scientific manner using this established format.

IMINI data loggers will be used to measure and record temperature. Each data logger has been calibrated and calibration certificates are included in each report generated. These electronic instruments are verified by Vacker Global instrumentation department and therefore, it was deemed that post calibration was not necessary. Associated document are available upon request.

CONSOLEPLUS Cold Chain Monitoring System or equivalent will be used to program data loggers, to download data and to generate reports which are compliant to PIC/S GMP Annex 11 and 21 CFR Part 11 requirements.

Any test function that does not have results which support the parameters defined in the approved protocol must be conclusively rationalized for their deviation and approved or the qualification will be considered invalid.

This protocol is only applicable for the Shipping box

Note: We will use any equivalent data loggers with calibration certificate as per actual site conditions and test schedule.

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6 APPLICABILITY

All Vacker Global and xxxxxx personnel, when performing the Performance Qualification of the shipping box shall follow this qualification protocol.

7 RESPONSIBILITY

This qualification protocol must be respected by all Vacker Global and xxxxx employees during processing. The responsibility of the Performance Qualification of the shipping box is attributed to the following:

Responsibilities		
Task	**Vacker Global**	**XXXXXXXXXXX**
Make available all documentation required for the Performance Qualification.	✓	✓
Collect information.	✓	✓
Write the protocol.	✓	
Review and approve the protocol.	✓	✓
Verify that all critical instrument of the equipment have a valid calibration date.		✓
Coordinate activity.	✓	✓
Execute the test described in the protocol.	✓	✓
Compile and analyze data.	✓	
Write the final report.	✓	
Revise and approve the final report.	✓	✓

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8 EQUIPMENT DESCRIPTION

The Shipping box is designed to maintain products temperatures between 2°C to 8°C during products transportation to meet Xxxxxx 's requirements.

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