GRAM
Biostorage you can depend on

Customer: _____

_____

_____

Location of installation: _____

_____

_____

Model: _____ SN: _____ Item number: _____
(manual)

The PQ consists of inspections of the correct operation of the cabinet under predefined conditions and procedures. Prerequisites for the PQ are IQ (Installation Qualification) and OQ (Operation Qualification), these must be concluded successfully prior to the initiation of the PQ.

This PQ is intended for the following product series:

**BioCompact, BioCompact II, BioPlus, BioMidi, BioUltra**

Revision 29/03/2019_003

Person responsible for the cabinet:

Name: _____
Date: _____
Signature: _____

Person responsible for test:

Name: _____
Date: _____
Company: _____
Signature: _____

Person responsible for verification of test:

Name: _____
Date: _____
Company: _____
Signature: _____

Test duration:

Initation (date/time): _____
Conlusion (date/time): _____

Model: _____ SN: _____

## Name list - *Persons involved in the test procedure and subsequent report*

| Date | Name | Company | Signature |
|---|---|---|---|
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Model: _____ SN: _____

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report.
The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

## Measurement - Prerequisites

| ID | DESCRIPTION | ACCEPTED YES | ACCEPTED NO |
|---|---|---|---|
| P-1 | The cabinet must be empty while conducting tests, ie without interior fittings such as drawers, shelves etc.<br><br>Attachment:<br><br>Notes: | | |
| P-2 | The measurements must be conducted in accordance to IEC 60068-3-5.<br><br>Attachment:<br><br>Notes: | | |
| P-3 | The positioning of the sensors in the cabinet must be documented with a sketch and/or a photograph.<br><br>Attachment:<br><br>Notes: | | |

| | Name: | Signature: | Approved (Yes / No): | Date: |
|---|---|---|---|---|
| Conducted by: | | | | |
| Inspected / verified by: | | | | |

Model: _____ SN: _____

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report.
The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

## Measurement - Prerequisites

| ID | DESCRIPTION | ACCEPTED YES | ACCEPTED NO |
|---|---|---|---|
| P-4 | Measurements made during the PQ tests must be documented and attached to the PQ.<br><br>Attachment:<br><br>Notes: | | |
| P-5 | Specify setpoint temperature: _____ °C<br><br>Specify the ambient temperature: _____ °C<br><br>Attachment:<br><br>Notes: | | |
| P-6 | Allowed tolerances - *Select the tolerance, according to the model being tested. Find model-specific tolerances in appendix.*<br><br>Tolerance: +/- _____ K<br><br>Attachment:<br><br>Notes: | | |

| | Name: | Signature: | Approved (Yes / No): | Date: |
|---|---|---|---|---|
| Conducted by: | | | | |
| Inspected / verified by: | | | | |

Model: _____ SN: _____

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report.
The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

## Measurement - Temperature stabilization

| ID | DESCRIPTION | ACCEPTED YES | ACCEPTED NO |
|---|---|---|---|
| P-7 | The test is intended to provide substantiation for the temperature stability inside the cabinet during normal operation.<br><br>The temperature inside the cabinet must be stabilized - where all the points in the working space have reached and maintained the same temperature.<br><br>When the system is stable, document ordinary operation of the cabinet at the setpoint temperature and ambient temperature specified in P-5.<br><br>Duration: _____<br><br>The measurements throughout the operation test, must be documented and attached the PQ.<br><br>Attachment:<br><br>Notes: | | |
| P-8 | Are the measurements inside the allowed tolerances specified in P-6 ?<br><br>Attachment:<br><br>Notes: | | |

| | Name: | Signature: | Approved (Yes / No): | Date: |
|---|---|---|---|---|
| Conducted by: | | | | |
| Inspected / verified by: | | | | |

Model: _____ SN: _____

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report.
The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

## Measurement - Door opening test

| ID | DESCRIPTION | ACCEPTED YES | ACCEPTED NO |
|---|---|---|---|
| P-9 | The test is intended to provide substantiation for the temperature recovery time inside the cabinet subsequently after a door opening.<br><br>The temperature inside the cabinet must be stabilized - where all the points in the working space have reached and maintained the same temperature, the setpoint temperature is specified in P-5.<br><br>When the system is stable, open the door at 90° for 60 seconds.<br><br>The measurements, throughout the door opening test, must be documented and attached the PQ.<br><br>Duration: _____<br><br>Attachment:<br><br>Notes: | | |
| P-10 | Has the setpoint temperature specified in P-5, measured in the absolute centre of the cabinet, been achieved within the set time-frame specified in the appendix?<br><br>Attachment:<br><br>Notes: | | |

| | Name: | Signature: | Approved (Yes / No): | Date: |
|---|---|---|---|---|
| Conducted by: | | | | |
| Inspected / verified by: | | | | |

Model: _____ SN: _____

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report.
The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

## Measurement - Pull-down

| ID | DESCRIPTION | ACCEPTED | |
|---|---|---|---|
| | | YES | NO |
| P-11 | The test is intended to provide substantiation for the time it takes for the inside of the cabinet to reach the setpoint temperature specified in P-5.<br>The initial temperature in the working space is the ambient temperature specified in P-5.<br>The temperature inside the cabinet must be stabilized in all points of the working space.<br><br>When the system is stable. Turn on the power to the cabinet.<br><br>The measurements, throughout the pull-down test, must be documented and attached the PQ.<br><br>Duration: _____<br><br>Attachment:<br><br>Notes: | | |
| P-12 | The time it takes the inside of the cabinet to achieve the setpoint temperature measured in the absolute centre, must not exceed the time-frame specified in the appendix.<br><br>Have the criteria been met?<br><br>Attachment:<br><br>Notes: | | |

| | Name: | Signature: | Approved (Yes / No): | Date: |
|---|---|---|---|---|
| Conducted by: | | | | |
| Inspected / verified by: | | | | |

Model: _____ SN: _____

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report.
The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

## Measurement - Hold-over

| ID | DESCRIPTION | ACCEPTED YES | ACCEPTED NO |
|---|---|---|---|
| P-13 | The test is intended to provide substantiation for the time it takes for the temperature inside the cabinet to reach the end temperature specified in the appendix.<br>Ambient temperature and setpoint temperature is specified in P-5.<br><br>The temperature inside the cabinet must be stabilized - where all the points in the working space have reached and maintained the same temperature throughout, the tolerances are specified in P-6.<br><br>When the system is stable, turn off the power to the cabinet.<br><br>The measurements, throughout the hold-over test, must be documented and attached the PQ.<br><br>Attachment:<br><br>Notes: | | |
| P-14 | The times it takes the inside of the cabinet to reach the end temperature, must at least be the time specified in the appendix.<br><br>Duration: _____<br><br>Have the criteria been met?<br><br>Attachment:<br>Notes: | | |

| | Name: | Signature: | Approved (Yes / No): | Date: |
|---|---|---|---|---|
| Conducted by: | | | | |
| Inspected / verified by: | | | | |

Model: _____ SN: _____

## Deviation Report

Deviations to the criteria of acceptance are to be documented in the deviation report. A separate deviation report shall be made for each deviation. Mark the entry with the relevant “P-ID” specified in the left column in the test specifications.

P-ID: _____

Description of deviation:

_____

_____

_____

_____

_____

Extent to which the deviation has been alleviated:

_____

_____

_____

_____

_____

Additional notes:

_____

_____

_____

_____

_____

| Person responsible for test: | Person responsible for verification of test: |
|---|---|
| Name: _____ | Name: _____ |
| Date: _____ | Date: _____ |
| Company: _____ | Company: _____ |
| Signature: _____ | Signature: _____ |

Model: _____ SN: _____

## Approval of test results - Performance Qualification (PQ)

◯ The steps in the Performance Qualification - PQ were completed with positive results

◯ The steps in the Performance Qualification - PQ were completed with negative results

ID of steps with negative results: _____

Additional notes:

_____

_____

_____

_____

_____

| Person responsible for test | Person responsible for verification of test |
|---|---|
| _____ | _____ |
| Stamp & Signature | Stamp & Signature |
| _____ | _____ |
| Tel. | Tel. |
| _____ | _____ |
| E-mail | E-mail |
| _____ | _____ |
| Location & Date | Location & Date |

Model: _____ SN: _____

NOTES:

Model: _____ SN: _____

## Appendix:

| | Model | Tolerances | Door opening - recovery time | Pull-down | Hold-over range* | Hold-over |
|---|---|---|---|---|---|---|
| RR | **BioCompact/BioCompact II** | | | | | |
| | 210 (Solid door) | +/- 3K | 5 Minutes | 25 Minutes | 5°C → 10°C | 55 Minutes |
| | 210 (Glass door) | | 6 Minutes | 35 Minutes | | 30 Minutes |
| | 310 (Solid door) | | 5 Minutes | 25 Minutes | | 55 Minutes |
| | 310 (Glass door) | | 6 Minutes | 30 Minutes | | 32 Minutes |
| | 410 (Solid door) | | 6 Minutes | 28 Minutes | | 62 Minutes |
| | 410 (Glass door) | | 7 Minutes | 35 Minutes | | 35 Minutes |
| | 610 (Solid door) | | 3 Minutes | 20 Minutes | | 66 Minutes |
| | 610 (Glass door) | | 3 Minutes | 25 Minutes | | 40 Minutes |
| | **BioMidi** | | | | | |
| | 425 (Solid door) | +/- 3K | 3 Minutes | 20 Minutes | 5°C → 10°C | 63 Minutes |
| | 425 (Glass door) | | 4 Minutes | 25 Minutes | | 37 Minutes |
| | 625 (Solid door) | | 3 Minutes | 20 Minutes | | 63 Minutes |
| | 625 (Glass door) | | 4 Minutes | 25 Minutes | | 37 Minutes |
| ER | **BioPlus** | | | | | |
| | 500 (Solid door) | +/- 2K | 3 Minutes | 22 Minutes | 5°C → 10°C | 72 Minutes |
| | 500 (Glass door) | | 4 Minutes | 28 Minutes | | 42 Minutes |
| | 600D / 600W (Solid door) | | 3 Minutes | 20 Minutes | | 70 Minutes |
| | 600D / 600W (Glass door) | | 4 Minutes | 25 Minutes | | 41 Minutes |
| | 660D / 660W (Solid door) | | 3 Minutes | 20 Minutes | | 70 Minutes |
| | 660D / 660W (Glass door) | | 4 Minutes | 25 Minutes | | 41 Minutes |
| | 930 (Solid door) | | 5 Minutes | 22 Minutes | | 65 Minutes |
| | 1270 / 1400 (Solid door) | | 5 Minutes | 23 Minutes | | 78 Minutes |
| | 1270 / 1400 (Glass door) | | 7 Minutes | 29 Minutes | | 45 Minutes |

* The temperature span between the initial temperature and the end temperature in the hold-over test P-13,14

Note:

RR/ER :
Ambient temperature +25°C
Setpoint temperature +5°C

| | Name: | Signature: | Approved (Yes / No): | Date: |
|---|---|---|---|---|
| Conducted by: | | | | |
| Inspected / verified by: | | | | |

Model: _____ SN: _____

## Appendix:

| | Model | Tolerances | Door opening - recovery time | Pull-down | Hold-over range* | Hold-over |
|---|---|---|---|---|---|---|
| RF | **BioCompact/BioCompact II** | | | | | |
| | 210 | ** | ** | 60 Minutes | -20°C → -10°C | 48 Minutes |
| | 310 | ** | ** | 60 Minutes | | 50 Minutes |
| | 410 | ** | ** | 62 Minutes | | 52 Minutes |
| | 610 | +/- 5K | 8 Minutes | 55 Minutes | | 55 Minutes |
| | **BioMidi** | | | | | |
| | 425 | +/- 5K | 9 Minutes | 45 Minutes | -20°C → -10°C | 55 Minutes |
| | 625 | | 8 Minutes | 42 Minutes | | 55 Minutes |
| | **BioPlus** | | | | | |
| | 500 | +/- 5K | 7 Minutes | 45 Minutes | -20°C → -10°C | 55 Minutes |
| | 600D / 600W | | 7 Minutes | 42 Minutes | | 55 Minutes |
| | 660D / 660W | | 7 Minutes | 42 Minutes | | 55 Minutes |
| | 930 | | - | 76 Minutes | | 63 Minutes |
| | 1270 / 1400 | | 10 Minutes | 45 Minutes | | 58 Minutes |
| EF | **BioMidi** | | | | | |
| | 425 | +/- 9K | 40 Minutes | 107 Minutes | -40°C → -10°C | 108 Minutes |
| | **BioPlus** | | | | | |
| | 600W / 660W | +/- 10K | 30 Minutes | 57 Minutes | -35°C → -10°C | 170 Minutes |
| UL | **BioUltra** | | | | | |
| | UL570 | +/- 5K | 45 Minutes | 300 Minutes | -80°C → -60°C | 150 Minutes |

* The temperature span between the initial temperature and the end temperature in the hold-over test P-13,14.
** Please contact your local distributor for current information.

Note:

RF:
Ambient temperature +25°C
Setpoint temperature -20°C

BioUltra UL570
Ambient temperature +25°C
Setpoint temperature -80°C

EF (425):
Ambient temperature +25°C
Setpoint temperature -40°C

EF (600W/660W):
Ambient temperature +25°C
Setpoint temperature -35°C

| | Name: | Signature: | Approved (Yes / No): | Date: |
|---|---|---|---|---|
| Conducted by: | | | | |
| Inspected / verified by: | | | | |

Model: _____ SN: _____