The following IQ / OQ is intended to be a guideline, local IQ / OQ procedures can vary depending on application and items stored in the Gram BioLine cabinet.
Deviations from the specifications dictated in the PQ are to be reported in the deviation report.

The IQ / OQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

This IQ / OQ is intended for the following product series:

BioBlood

Revision: 10/10/2017_001

Customer:

_____

_____

_____

Location of installation:

_____

_____

_____

Model:

_____

Serial number:

_____

Item number - manual:

_____

Status of operation:

○ Active

○ Inactive

Name of distributor:

_____

_____

_____

Warranty:

Start: _____

End: _____

Instructions on use to starting the cabinet:

1. Training of the responsible party Date: _____ By: _____

2. Operational test of the cabinet Date: _____ By: _____

3. Responsible party _____ Tel: _____

Instructions to users:

The responsible party is trained in use of the cabinet in reference to the user manual

- ◯ General use of cabinet
- ◯ Service & maintenance
- ◯ The cabinet was delivered without defects/damage. The cabinet started as specified in the user manual

Objections to the mentioned:

_____

_____

_____

_____

Set values:

◯ Setpoint temperature _____ °C

Local alarm settings

◯ High temperature alarm _____ °C

◯ Low temperature alarm _____ °C

External alarm settings
(See voltage free contact in user manual)

◯ High temperature alarm _____ °C

◯ Low temperature alarm _____ °C

Factory settings:

Model / Setpoint temp.		LHL	LLL	EHL	ELL
BF	-20 °C	+25 °C	-35 °C	+25 °C	-35 °C
PF 425	-40 °C	+25 °C	-60 °C	+25 °C	-60 °C
PF 6XXW	-35 °C	+25 °C	-45 °C	+25 °C	-45 °C
BR	+4 °C	+6 °C	+2 °C	+25 °C	0 °C

Date:	Name of trained user:	Signature:	Name of instructor:	Signature:

Model: _____ SN: _____

Installation Qualification - IQ

ID	Description of installation	Reference in manual	Comply YES	Comply NO	Attachmet	Notes
I-1	Ensure the cabinet is installed indoors.	Page 4				
I-2	Ensure the cabinet is installed in a sufficiently dry/ventilated area.	Page 4				
I-3	Ensure the cabinet is not in direct contact with sunlight or other heat sources.	Page 4				
I-4	Ensure that the temperature operating range is correct.	Page 4				
I-5	Ensure that the cabinet is not installed in a corrosive environment.	Page 4				
I-6	Ensure that the protective film on the cabinet is removed.	Page 4				
I-7	Ensure that the cabinet is cleaned.	Page 4				
I-8	Ensure that the cabinet has stood upright for 24 hours if it has lain down.	Page 4				
I-9	Ensure that the cabinet is levelled if it is equipped with legs.	Page 4				
I-10	Ensure a level surface if the cabinet is equipped with wheels/casters.	Page 4				
I-11	- If equipped with wheels/casters - Ensure wheels/casters are locked after positioning.	Page 4				
I-12	- If equipped with drawers / glass door - Ensure that tilt-bracket is mounted.	Page 5				
I-13	Ensure that the cabinet is maximum 75mm from the back wall.	Page 6				
I-14	Ensure that there is minimum a gap of 30mm between cabinets.	Page 6				
I-15	Ensure that the top of the cabinet is not covered. (applicable to 500, 6xx, 1270/1400).	Page 6				
I-16	Ensure that the holes in the front of the cabinet are not covered.	Page 6				

Model: _____ SN: _____

Installation Qualification - IQ

ID	Description of installation	Reference in manual	Comply YES	Comply NO	Attachmet	Notes
I-17	Ensure that electrical appliances are not being used in the cabinet.	Page 6				
I-18	Ensure connection from voltage-free contact to external monitoring system (optional).	Page 7				
I-19	Ensure the correct set-point for the low temperature protection (if applicable).	Page 8				
I-20	Ensure the correct electrical connection (compare local values with type/nr plate).	Page 9				
I-21	Ensure that the power cord is secured in the terminal box with hanger.	Page 9				
I-22	Mark power cord with: “Do not separate when energized”.	Page 9				

Model: _____ SN: _____

Operation Qualification - OQ

ID	Description of operation	Reference in manual	Comply		Attachmet	Notes
			YES	NO		
O-1	Turn on the cabinet - Display test (software version and variant).	Page 10				
O-2	Set/adjust set-point temperature.	Page 10				
O-3	Set/adjust LHL - Upper alarm limit (local).	Page 15				
O-4	Set/adjust LLL - Lower alarm limit (local).	Page 15				
O-5	Set/adjust LHd - delay for upper alarm limit (local).	Page 16				
O-6	Set/adjust LLd - delay for lower alarm limit (local).	Page 16				
O-7	Activate / deactivate dA - door alarm (local).	Page 17				
O-8	Set/adjust dAd - delay for door alarm (local).	Page 17				
O-9	Activate / deactivate bU - acoustic alarms (local).	Page 18				
O-10	Set/adjust EHL - Upper alarm limit (external).	Page 19				
O-11	Set/adjust ELL - Lower alarm limit (external).	Page 19				
O-12	Set/adjust EHd - delay for upper alarm limit (external).	Page 20				
O-13	Set/adjust ELd - delay for lower alarm limit (external).	Page 20				
O-14	Activate / deactivate dA - door alarm (external).	Page 21				
O-15	Set/adjust dAd - delay for door alarm (external).	Page 21				
O-16	Activate / deactivate bU - acoustic alarms (external).	Page 22				
O-17	Set/adjust defrost cycles per 24 hours (factory setting: 4).	Page 24				
O-18	Select reference sensor for the display (A or E).	Page 25				

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 "-ID" specified in the left column in the test specifications.

-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 - Installation Qualification (IQ)

◯ The steps in the Installation Qualification - IQ were completed with positive results

◯ The steps in the Installation Qualification - IQ were completed with negative results

ID of steps with negative results: _____

Approval of test results - Operation Qualification (OQ)

◯ The steps in the Operation Qualification - OQ were completed with positive results

◯ The steps in the Operation Qualification - OQ were completed with negative results

ID of steps with negative results: _____

Customer / Responsible party	Trainer / Responsible party
Stamp & Signature	Stamp & Signature
Tel.	Tel.
E-mail	E-mail
Location & Date	Location & Date

Model: _____ SN: _____

NOTES:

Model: _____ SN: _____