AUTOCLAVE VALIDATION REPORT

(FM/VRB-114)

SURGICON (Pvt) Ltd

Khadim Ali Road Sialkot, Pakistan

Approval

	NAME	DATE	SIGNATURE
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Review By:	Abdul Wahid (General Manager)	25/09/2024	Abdul Wahid
Approved By:	Imtinan Jilani (Director)	25/09/2024	Imtinan Jilani

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Process Validation Protocol

OBJECTIVES:

It is required to autoclave test our Surgical Instruments parts within the quality range of ISO standards using calculated volume of test number of instruments with time.

PRODUCTS TO BE COVERED:

All kind of surgical, Dental, TC Inserts,

EQUIPMET/PROCESS TO BE VALIDATED:

Autoclave test Process

NUMBER OF MACHINE USED: 01 Machines

Specification:

Length: 36 Inches

Width: 24 Inches

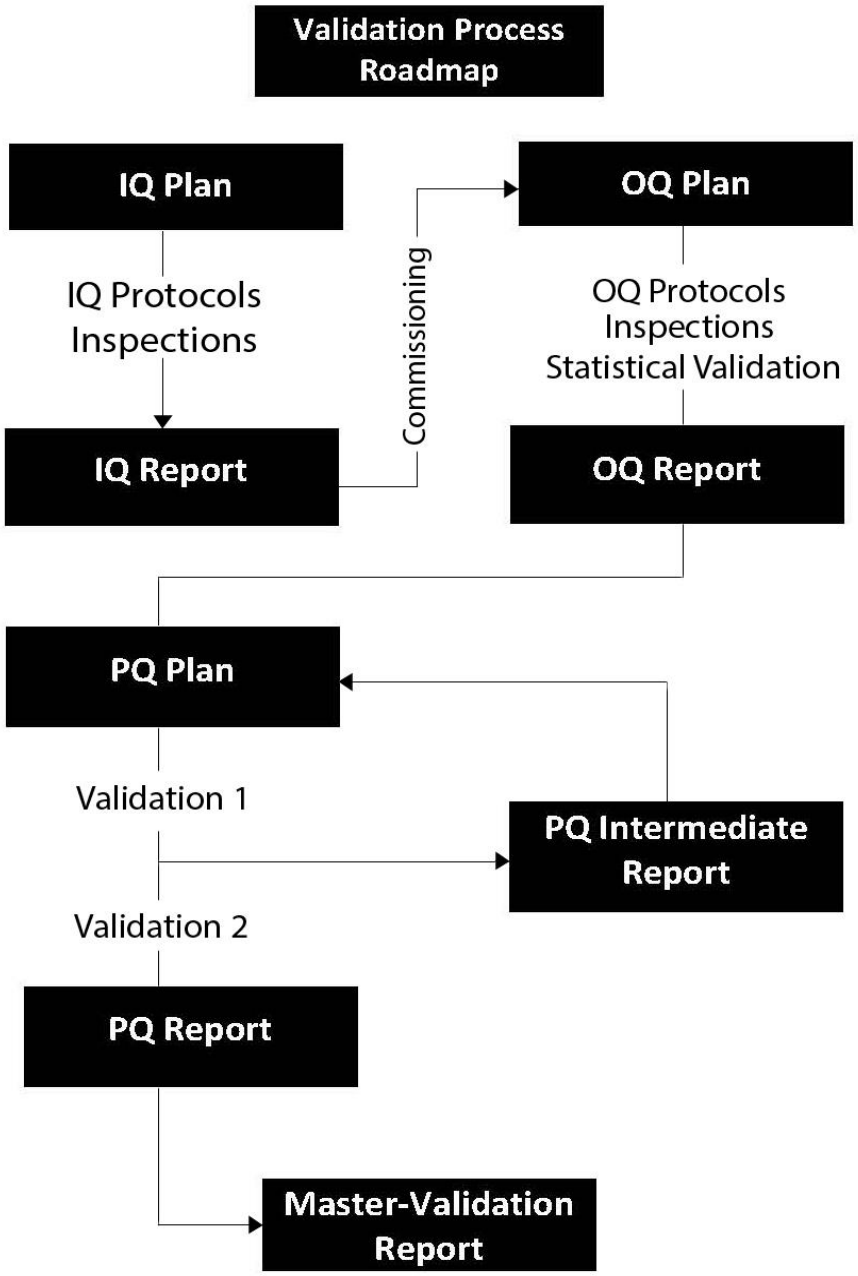
Height: 24 Inches

VALIDATION TEAM PROTOCOAL

_____	_____
Imtinan Jilani ((Director Production & QA)	Abdul Wahid (General Manager)
_____	_____
M. Arshad Malik (QA & RA Manager)	Sohail Javed (Machine Operator)

VALIDATION PLAN

Auto Clave Test process will be subjected to installation qualification, operational qualification, and performance qualification. The **Installation Qualification**: of Autoclave Test machine used for autoclave test process to define requirements for heating, parameters, Volume and heater temperatures. The second phase of validation is **Operational Qualification** that will determine the sensitivity of the process to variation in time, temperature, quantity. with a short time, dwell, high temperature, 134 Degree: with a long time, Action level for the adjustment of tank will be determined as a result of this phase.



Performance Qualification: will commence after satisfactory completion of operational qualification. Optimal setting for autoclave machine will be used and samples will be subjected to clean and results will be determined. When process stability is demonstrated and process gives results in the required range the process will be validated and will be used to control the process.

1: INSTALLATION QUALIFACTION.

- **i) Dimensions: 36x24x24 inches**
- **ii) Immersion**
- **iii) Vapour Zone**

1) **Temperature**
   There are heater used in autoclave test to provide temperature of the machine. the temperature of the machine will be 134 degrees when the instruments autoclave.
2) **Volume of Container.**
   There are 1 main tank containing water, 50 litters. So total capacity or working volume of tank is 50 Litters.

3) **Time/Stop watch**:
   Overall, 40 to 50 minutes are useful for dipping and steaming with respect to the size of the product to control growth and bio burden. If we increase the heating time, then product starting to become red/brown shade and product final shining finish effecting. So we consider the above timing is ideal for autoclave testing process

2: OPERATIONAL QUALIFICATION:

SELECTION OF DEVICES: Choice of Instruments.

A number of instruments from the range sold by the company were assembled to represent the various groups and classes of instruments. Each selected instrument was intended to represent the most difficult aspects of the boil test for that group. For example, Sponge Holding Forceps 24 cm will cover the range of our all the small sizes items etc. However, the features of some of the instruments can also be used to demonstrate compliance of the other instruments not categorised in their group.

Risk Analysis:

A risk analysis was then done to identify the features considered to require validation of reprocessing capability. If these features pass validation, then other instruments containing any of those features are considered to have been validated.

Table 1 - Selected Instruments.

Device Name	Description and characteristics.
Crile Forceps	These are locking forceps adapted for a variety of purposes including holding and positioning of swab, grasping and manipulating cervical tissues.
Dressing Scissors	Specialized scissors adapted to cut heavy or thick bandaging, especially to remove them from patients. They are also widely used to remove orthopaedic casting.
Needle Holder	These forceps are adapted to grasping fascia, heavier tissues and handling larger needles. They are generally used for tasks such as perinea surgery and the removal of stones from gall bladder
Dental Pliers (Dental Instruments)	Used to loosen to pull the tooth from the periodontal Socket

For the second test the following devices were selected to demonstrate that sterility could be achieved:

Forceps	These are locking forceps adapted for a variety of purposes including holding and positioning of swab, manipulating cervical tissues
Vaginal Speculum (Gynaecological devices)	The vaginal speculum devices are used to open the vagina and provide access to the cervix gynaecological or Obstetrical examination and procedures.

In the selecting the representative devices the degree of difficulty in autoclaving, the materials used and the end use were taken into consideration as shown in the table below.

Criteria	Device
Small Deep bores	Vaginal speculum Dental Pliers Forceps
Pivot joints	Vaginal Speculum Ads on Toothed Forceps

	Tissue Forceps
Ingress of contaminations into the internal areas of the device	Vaginal speculum Dressing Scissor Mikulicz peritoneal Forceps Dental Pliers

OPERATIONAL QUALIFICATION RESULTS:

Experiment # 01 Lot # FCP-29041-0170

S #	TIME	TEMPERATURE	RESULT
01	35 minutes	85	Not Good
02	40 minutes	95	Not Good
03	48 minutes	132	Excellent

Experiment # 02 Lot # FCP-270417-0178

S #	TIME	TEMPERATURE	RESULT
01	30 minutes	90	Not Good
02	40 minutes	100	Not Good
03	50 minutes	134	EXcellent

Phase 2:

Ideal Case production process was used to autoclave the instruments on machine

i) 1st heater is adjusted at 134 degrees and time 6 Degree.
ii) Time 50 minutes for heating.
iii) Total Volume of Water used is 50 litters.

Results:

The run with optimal setting results in a good and desired autoclave and surface appearance.

The Time 50 minutes and temperature 134 degree is suitable for the autoclave test.

3: Performance Qualification:

Normal production of Mentioned products was run at optimal ideal settings. Results obtained were control charted. Following is the typical control chart between the Quantity boiled.

The comparison results for each activity demonstrated that the process was stable.

Result:

The process has demonstrated stability. The process validation plan has been updated to include the validation of Boil Test.

Validation Results Approval

We have reviewed the requirements of the protocol; the IQ, OQ and PQ reports and compared these to the requirements of the reference documents. All requirements have been met and the process is validated.

REVALIDATION:

Upon completion of validation, the process validation plan will be updated to include the validation of Autoclave Test e in the master validation schedule.

Studies were conducted to determine the effect of key inputs on cleaning and shade of productises surface, which is resulted after Autoclave Test. Variations in setting are used and the resultant autoclave of mentioned pieces of stainless steel were calculated. The following table summarizes the results and variations in all these parameters (especially in temperature) will result in change in final result.

Approval of Validation Team.

_____	_____
Imtinan Jilani ((Director Production & QA)	Abdul Wahid (General Manager)
_____	_____
M. Arshad Malik (QA & RA Manager)	Sohail Javed (Machine Operator)

Date: 25/09/2024