Steriliser Validation

2023

Eakin Healthcare - Surgical

**Pre-validation Questionnaire**

**Document Information**

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| --- | --- |
| Prepared By: | Date: |
| Project Ref: | Revision No.: |
| Document Name: |  |

# 1. Introduction

The purpose of this document is to clarify the requirements of the customer during the validation process. Please answer the questions as fully as possible as these will help ensure the best outcome from the validation by allowing us to understand your products and processes.

# 2. Validation Approach

2.1 The Performance Qualification will consist of three half cycles (ISO 11135 Annex B – Overkill approach) and one additional dedicated Physical PQ run on single configuration.

# 3. Questionnaire

3.1 Products to be selected during the validation

3.1.1 List the products below with a description of their construction (if all technical details are already available in an existing document this may be referred to and attached);

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Product Name | Product Code | Product Material | Packing Description | Construction Materials |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

3.1.2 Please indicate if any of the products above have already been defined in a ‘product family’

|  |
| --- |
| Product family details:  Click here to enter text. |

3.1.3 If a ‘product family’ is already defined please state the identified ‘worst case’ item in terms of challenge to sterilisation:

|  |
| --- |
| Worst case items:  Click here to enter text. |

3.1.4 Do any of the products present any special sterilisation challenges as follows:

3.1.4.1. Lumens/tubing?;

Click here to enter text.

3.1.4.2. Highly absorbent materials?

Click here to enter text.

3.1.4.3 Other: valves, seals, gas impenetrable areas or restrictive packaging?

Click here to enter text.

3.2 Packaging/configuration

3.2.1 Please describe the normal size of the packaging and size of the cardboard secondary containers (if used);

|  |
| --- |
| Item size:  Click here to enter text.  Secondary cardboard dimensions:  Click here to enter text.  Item quantity in each secondary container:  Click here to enter text. |

3.2.2 Do you have a pre-existing load configuration/method? If so please state the document reference below and attach the document.

Click here to enter text.

3.2.3 Does your current load configuration give consideration to heat, humidity and gas exchange? If so please describe in terms of structural features;

|  |
| --- |
| Features:  Click here to enter text. |

3.2.4 Are products mixed in each pallet or dedicated?

Click here to enter text.

3.2.5 Current pallet dimensions;

Click here to enter text.

3.3 Process challenge devices

3.3.1 Do you have a specific external process challenge device that you are currently using with your products? Please give details;

|  |
| --- |
| Process challenge device;  Click here to enter text. |

|  |  |
| --- | --- |
| Completed by: | Click here to enter text. |
| Date completed: | Click here to enter text. |