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DOCUMENT APPROVAL

Author's Signature:

Your signature indicates that this document has been prepared in accordance with company standards or guidelines and adequately reflects the tasks and deliverables necessary.

Signature	.....	**Date**	01 Mar 2018
Print Name	Gary Crawley		
Title	QA & Systems Manager Subject Matter Expert		

Reviewer's Signature:

Your signature indicates that, you have reviewed this document and that it accurately and completely reflects the tasks and deliverables necessary.

Signature	.....	**Date**	1 Mar 2018
Print Name	Stephen Harris		
Title	Head of Medical Production (AEUS) System Owner		

Signature	.....	**Date**	01st Mar 18
Print Name	Dean Yeomans		
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Quality Assurance/Compliance Approver's Signature:

Your signature indicates that this document complies with company standards or guidelines; and that the documentation and information contained herein complies with applicable regulatory, corporate, divisional/departmental requirements, and current Good Manufacturing Practices.

Signature	.....	**Date**	02 Mar 18
Print Name	Gary Crawley		
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1.0 PURPOSE

1.1. The purpose of the document is to define the procedures to be followed by Advanex Europe Ltd, to re-validate processes to ensure that the original validation status and conditions are maintained.

2.0 SCOPE

2.1. This process is applicable to all processes used to manufacture or process parts, supplied for use in a medical product

3.0 TERMS, DEFINITIONS & ABBREVIATIONS

3.1. Formal validation: Validated in accordance with a Validation Master Plan

3.2. Unrecorded change: Any change that has not been formally approved as defined in SOPPH/001 (Change Control)

3.3. Periodical re-validation: A revalidation exercise performed at set frequencies to ensure that the validated status and condition are maintained.

3.4. Re-validation of a changed process: Any validation performed to approve a change to a previously validated process.

4.0 HEALTH, SAFETY & ENVIRONMENTAL

4.1. Eye protection and safety footwear must be worn on the shop floor area

5.0 ASSOCIATED DOCUMENTS

5.1. Associated paperwork

5.2.Functional design specification (FDS)

5.3. Design Qualification summary sheet (DQ)

5.4. Installation Qualification summary sheet (IQ)

5.5. Operational Qualification summary sheet (OQ)

5.6. Process Qualification summary sheet (PQ)

5.7. Validation Master Plan (VMP)

5.8. Re-validation test protocol

5.9. Re-validation summary

5.10. Change control procedure - AEU00200

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6.0 PROCEDURE

6.1. Frequency of re-validation

6.1.1. Any process subject to formal validation will be re-validated every 36 months from the date of PQ approval.

6.2. Planning

6.2.1. Test protocols will be produced and approved to ensure that the original validation conditions are still applicable.

6.2.2. The test protocols will be designed to identify any unrecorded changes to:

6.2.2.1. The design of the of the process in relation to the original FDS and DQ Summary report

6.2.2.2. The installation of the process in relation to the IQ summary report.

6.2.2.3. The operation and performance of the process in relation to OQ and PQ. This will include the re-verification of all critical devices.

6.2.3. Out puts from periodical re-validation

6.2.3.1. Any unrecorded changes identified will be communicated to the customer(s)

6.2.3.2. A review of the changes will be held to establish;

6.2.3.3. Why the change occurred without adherence to AEU00200

6.2.3.4. The potential impact of the change to the process and product.

6.2.3.5. The need for the full or partial validation / approval exercise to be repeated

6.3. Any changes approved in accordance to AEU00200 will be recorded during the re-validation exercise.