Unit Title: Manufacture Equipment or Medical Devices for Individuals Within Healthcare	
Level:	Three
Credit Value:	4
GLH:	30
OCNLR Unit Code:	PA1/3/LQ/060
Ofqual Unit Reference Number:	F/508/3934

This unit has 5 learning outcomes

LEARNING OUTCOMES	ASSESSMENT CRITERIA
The learner will:	**The learner can:**
1. Understand current legislation, national guidelines, policies, protocols and good practice related to manufacture of medical devices.	1.1. Summarise the current legislation, national guidelines, policies, protocols and good practice guidelines for the manufacture of equipment or medical devices. 1.2. Explain how the prescription requirement is integrated in the manufacture of equipment or medical devices. 1.3. Describe how to assess and manage risks within the manufacturing environment and for the item under construction.
2. Prepare to carry out the manufacturing of equipment or medical devices.	2.1. Identify and assess existing manufacturing components for suitability. 2.2. Select the materials, tools and techniques for producing the equipment or device. 2.3. Interpret the specification for the manufacture of the equipment or device. 2.4. Determine those aspects of specification which relate to an adaptation of existing equipment and/or device to meet the prescribed customised solution.
3. Carry out the manufacturing of equipment or medical devices.	3.1. Work with stakeholders and others involved in the manufacture process. 3.2. Implement health and safety measures relevant to the manufacturing of equipment or medical devices. 3.3. Manufacture and assemble the component parts to the agreed specification.

4. Monitor operations and conditions.	4.1. Maintain environmental conditions as required by the manufacturing procedure. 4.2. Carry out the testing, monitoring, inspection and risk assessment for the operation of equipment and materials. 4.3. Respond to any faults or breakdowns to equipment in line with local policy and protocol.
5. Test and adjust the finished equipment or medical device.	5.1. Confirm that the product meets agreed specification, prescription and performance parameters. 5.2. Apply standard precautions for infection control. 5.3. Test the product with the individual. 5.4. Adapt the product to meet the customised solution. 5.5. Compile and maintain records and user information for the equipment or medical device in line with local policy and protocol. 5.6. Store records in line with local policy and protocol.

Assessment

The grid below gives details of the assessment activities to be used with the unit attached.
Please refer to the OCN London Assessment Definitions document for definitions of each activity and the expectations for assessment practice and evidence for verification.

P = Prescribed This assessment method *must* be used to assess all or part of the unit.

O = Optional This assessment method *could* be used to assess all or part of the unit.

Case Study		Project	
Written question & answer/test/exam	O	Role play/simulation	
Essay		Practical demonstration	P
Report		Group discussion	
Oral question and answer	O	Performance/exhibition	
Written description	O	Production of artefact	
Reflective log/diary		Practice file	