D-722-4-1 PRE-SHIPMENT AUDIT_V1

Product Conformity Assessment

This assessment assures medical device buyers or manufacturers that their suppliers or OEMs manufacture product(s) in full conformance with the user, technical and regulatory requirements.

Critical Component Assessment

Critical components like lithium-ion battery or power supply are essential for the safety and performance of the finished product. Assessment on the supplier's details and/or incoming inspections could ensure adherence to the technical file and compliance to technical specifications stated on technical file.

Sterilization Process Assessment

This assessment ensures the sterilization process used by the suppliers or OEMs is fully validated and effectively managed. This evaluation includes the review of:-

a) Validation documentation

b) Product bioburden level

c) Specific procedure(s) selected,

d) Control and monitoring methods,

e) Record maintenance process

f) Personnel employed to implement the sterilization process.

Process Validation Assessment

Process validation assessment ensures OEM(s) and Suppliers validate production processes in which the resulting output cannot be verified by subsequent monitoring or measurement. This includes sterile packaging sealing, clean room ambient condition, aseptic filling, plating, welding, soldering and injection moulding.

Product Performance Testing

This is conducted to ensure the products manufactured conform to the specifications laid down in the technical file and are good for market release.

Packaging and Labelling Assessment

Packaging and Shipping Mark Assessment

This assessment ensures the correct pack configuration and shipping mark is employed and conforms to the specification stated in the technical file.

UDI / Barcode Check

This affirms the correct barcode /UDI label is being installed.