## Design, Manufacturing Information

### Device Design Information

#### The Spectra Optia Apheresis System has been developed in accordance with applicable portions of ISO 13485: 2003.

The Spectra Optia Apheresis System software has been developed in accordance with applicable portions of IEC 62304: 2005.

### Manufacturing Processes through Shipment

Raw materials and components are ordered from approved suppliers. Once the components are received they are inspected in accordance with the requirements set out in the product specification. If the parts pass inspection they are released and are moved to the warehouse for staging.

Manufacturing requests the parts and they are moved from the warehouse into manufacturing and are verified with an in process check to insure they are the correct parts and that they have been released.

Parts are staged on the production floor. If required subassemblies are built and inspected and released waiting to be used to manufacture a machine. Subassemblies are inspected and this is documented.

The final assembly of the machine is done using released parts and subassemblies. The assembly is documented in the Device Master Record as well as any in process inspections that are done.

All finished machines are moved to functional checkout where the machine is operated and goes through the final testing and release.

The checkout machine is released and moved to packaging where it is packaged in accordance with the specifications and labeled.

The packaged machine is then shipped.

The equipment manufacturing process is summarized in a flow chart in **Attachment 3-1**.

The disposable set manufacturing process is summarized in a flow chart in **Attachment 3-2**.

### Design and Manufacturing Sites

The Spectra Optia Apheresis System equipment, software, and disposables are designed at

Terumo BCT, Inc.

10811 West Collins Avenue

Lakewood, CO 80215

USA

The manufacturing site for the **Spectra Optia Apheresis System**, both machine and disposable sets is

Terumo BCT, Inc.

10811 West Collins Avenue

Lakewood, CO 80215

USA

The sterilization of the **Spectra Optia** disposable tubing sets occurs at:

Terumo BCT Sterilization Services

11308 West Collins Avenue

Lakewood, CO 80215   
USA

#### The QMS certificates for these sites can be found on [MyWorkNet](http://myworknet.bct.gambro.net/learn/locate-corporate-records/certificates-and-declarations-of-conformity/Pages/default-global.aspx#topic) under

#### Learn

#### Locate Corporate Records

# Certificates and Declarations Of Conformity

#### 