

Subject: ISO 11607-1:2006 and ISO 11607-2:2006

To whom it may concern, the following is SteriPack's compliance statement with regard to ISO 11607-1:2006 and ISO 11607-2: 2006

**ISO 11607 Part 1 statement:**

The materials and test methods used at SteriPack to produce preformed sterile barrier system meet the applicable requirements of ISO 11607 Part 1.

The products we supply are customer specific and it is the responsibility of the customer to validate the final sterile barrier system to ensure that the material and package performance is appropriate for the product, sterilisation and distribution. Therefore these are areas outside the scope of responsibility for SteriPack.

**ISO 11607 Part 2 statement:**

SteriPack pouching machines are validated in line with the requirements outlined in ISO 11607-2. Individual pouch validations can be completed according to ISO 11607-2 at customer request. Quotations can be provided at customer request.

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