CLAIMS

1. Device for sterilising flexible bags, characterised in that it comprises a sterilisation zone formed by at least two electron accelerators that emit electron beams at different energies.

2. Device for sterilising flexible bags according to claim 1, characterised in that it comprises at least one accelerator that emits an electron beam at an energy of between 450-500 keV and at least one other accelerator that emits an electron beam at an energy of 700 - 750 keV.

3. Device for sterilising flexible bags according to claim 1, characterised in that it has an accelerator that emits an electron beam at an energy of between 450-500 keV and an accelerator that emits an electron beam at an energy of 700 - 750 keV.

4. Device for sterilising flexible bags according to any one of claims 1 to 3, characterised in that the accelerators are positioned on opposite sides of the bags in a position facing each other.

5. Device for sterilising flexible bags according to any one of claims 1 to 3, characterised in that the accelerators are positioned on opposite sides of the bags in a position in which they do not face each other.

6. Method for sterilising flexible bags containing a solution of human plasma proteins by electron beam, characterised in that it comprises the following steps:

a) at least one emission of an electron beam at an energy of between 450-500 keV;
b) after a period of approximately between 10 ns, emission of at least one second electron beam pulse at an energy of between 700 - 750 keV.

7. Method according to claim 6, characterised in that the distance from the flexible bag to be sterilised to the irradiation source is between 1.5 cm and 2.5 cm.

8. Method according to claim 7, characterised in that the distance from the flexible bag to be sterilised to the irradiation source is 2 cm.

9. Method according to any one of claims 6 to 8, characterised in that the bags to be sterilised can contain a volume of 50 mL to 500 mL.

10. Method according to any one of claims 6 to 9, characterised in that the solutions contained in said flexible bag are pharmaceutical solutions of biological origin, such as blood or blood products such as plasma, serum, red blood cells, albumin, α1-antitrypsin, von Willebrand factor, coagulation factors such

as factor VII, factor VIII and factor IX, immunoglobulins, plasminogen, plasmin, antithrombin III, fibrinogen, fibrin, thrombin or combinations thereof.

11. Method according to claims 6 to 10, characterised in that the pharmaceutical solutions are obtained by chemical synthesis, recombinant production or transgenic production.

12. In-line method for filling flexible bags, characterised in that it comprises the steps of:

a) labelling the bags;
b) sterilising the bags by electron beam, using the method according to claims 6 to 11;
c) filling the bags with the solution of human plasma proteins in a sterile environment; and
a) sealing the bags.

13. Method according to claim 12, characterised in that the bags to be sterilised can contain a volume of 50 mL to 500 mL.

14. Method according to either claim 12 or claim 13, characterised in that the solutions contained in said flexible bag are pharmaceutical solutions of biological origin, such as blood or blood products such as plasma, serum, red blood cells, albumin, α1-antitrypsin, von Willebrand factor, coagulation factors such as factor VII, factor VIII and factor IX, immunoglobulins, plasminogen, plasmin, antithrombin III, fibrinogen, fibrin, thrombin or combinations thereof.

15. Method according to claims 12 to 14, characterised in that the pharmaceutical solutions are obtained by chemical synthesis, recombinant production or transgenic production.